Nos. 78-911 & 78-1036

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

and

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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CASES	Page
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Burlington Truck Lines, Inc. v. *United States*, 371 U.S. 156 (1962)	82
Castle & Cooke Foods, a Division of Castle & Cooke, Inc., 5 BNA OSHC 1435, 1977-78 CCH OSHD ¶ 21,854 (1977), *appeal docketed*, No. 77-2565 (9th Cir., July 14, 1977)	61
Champlin Petroleum v. *OSHRC*, 593 F.2d 637 (5th Cir. 1979)	40
Consolidated Edison Co. v. *NLRB*, 305 U.S. 197 (1938)	82

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Consolo v. *Federal Maritime Commission*, 383 U.S. 607 (1966)	82
Continental Can Company, 4 BNA OSHC 1541, 1976-77 CCH OSHD ¶ 21,009 (1976)	60,61, 62,63
D.D. Bean & Sons v. *Consumer Product Safety Commission*, 574 F.2d 643 (1st Cir. 1978)	65
Dry Color Manufacturers Association v. *Department of Labor*, 486 F.2d 98 (3d Cir. 1973)	82
Environmental Defense Fund, Inc. v. *Environmental Protection Agency*, 465 F.2d 528, 150 U.S. App. D.C. 348 (1972)	68,69
Environmental Defense Fund, Inc. v. *Ruckelshaus*, 439 F.2d 584, 142 U.S. App. D.C. 74 (1971)	68
Federal Communications Commission v. *American Broadcasting Co.*, 347 U.S. 284 (1953)	59
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Federal Power Commission v. *Texaco Inc.*, 417 U.S. 380 (1974)	78
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Hess & Clark, Division of Rhodia, Inc. v. *Food and Drug Administration*, 495 F.2d 975, 161 U.S. App. D.C. 395 (1974)	38
Industrial Union Department, AFL-CIO v. *Bingham*, 570 F.2d 965, 187 U.S. App. D.C. 56 (1977)	12

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Industrial Union Department, AFL-CIO v. *Hodgson*, 499 F.2d 467, 162 U.S. App. D.C. 331 (1974)	64,65,70, 71,82
International Union (UAW) v. *OSHRC*, 557 F.2d 607 (7th Cir. 1977)	62
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National Realty and Construction Co. v. *OSHRC*, 489 F.2d 1257, 160 U.S. App. D.C. 133 (1973)	40
NLRB v. *Metropolitan Life Insurance Co.*, 380 U.S. 438 (1965)	82
Republic Granite Co., Inc., 4 BNA OSHC 1711, 1976-1977 CCH OSHD ¶ 21,167 (1976)	63
RMI Co., 6 BNA OSHC 1523, 1978 CCH OSHD ¶ 22,674 (1978), *rev'd*, *RMI Co.* v. *Secretary of Labor*, 594 F.2d 566 (6th Cir. 1979)	61
RMI Co. v. *Secretary of Labor*, 594 F.2d 566 (6th Cir. 1979)	63,64
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Securities and Exchange Commission v. *Sloan*, 436 U.S. 103 (1978)	56,57
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Society of the Plastics Industry v. *OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975)	64,65
Southeastern Community College v. *Davis*, 47 U.S.L.W. 4689 (June 11, 1979)	65

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Southern Railway v. *OSHRC*, 539 F.2d 335 (4th Cir.), *cert. denied*, 429 U.S. 999 (1976)	61
Stearns Electric Paste Co. v. *Environmental Protection Agency*, 461 F.2d 293 (7th Cir. 1972)	67
Synthetic Organic Chemical Manufacturers Association v. *Brennan*, 503 F.2d 1155, (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975)	70,71,82
Tennessee Valley Authority v. *Hill*, 437 U.S. 153 (1978)	36
Texaco Inc. and Oil, Chemical & Atomic Workers Union, 1978 CCH OSHD ¶ 23,068 (1978) (OSHRC Review Pending)	63
Titanium Metals Corp. of America v. *Usery*, 579 F.2d 536 (9th Cir. 1978)	40
Train v. *NRDC*, 421 U.S. 60 (1975)	56
Turner Co., Division of Olin Corp., 4 BNA OSHC 1554, 1976-1977 CCH OSHD ¶ 21,023 (1976), *rev'd*, *Turner Co.* v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977)	61
Turner Co. v. *Secretary of Labor*, 561 F.2d 82 (7th Cir. 1977)	62,63,64
United Parcel Service of Ohio, Inc. v. *OSHRC*, 570 F.2d 806 (1978)	64
United States v. *Rutherford*, 74 U.S.L.W. 4724 (June 19, 1979)	38
Walling v. *Portland Terminal Co.*, 330 U.S. 148 (1947)	66
West Point Pepperell, Inc., 5 BNA OSHC 1257, 1977-1978 CCH OSHD ¶ 21,751 (1977), *aff'd*, *Marshall* v. *West Point Pepperell, Inc.*, 588 F.2d 979 (5th Cir. 1979)	61
Worley Brothers Granite Co., 4 BNA OSHC 2042 (1977)	63
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21 U.S.C. § 360(b)(d)(1)(H) 10c
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29 U.S.C. § 655(f) 25,54,79, 21b

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30 U.S.C.A. §§ 801 *et seq.* (Supp. 1979) 44
30 U.S.C.A. § 811(a)(6)(A) (Supp. 1979) 44
30 U.S.C.A. § 811(d) (Supp. 1979) 44
30 U.S.C. § 841(b) 44
33 U.S.C. § 701 *et. seq.* 1c
33 U.S.C. § 1311(b)(2)(A) 67
29 C.F.R. § 1910.1000 7
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115 Cong. Rec. 2657 44
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123 Cong. Rec. S10289-90 45
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H.R. REP. NO. 95-312, 95th Cong., 1st Sess. (1977)	44
S. REP. NO. 95-181, 95th Cong., 1st Sess. (1977)	44
S. REP. NO. 95-312, 95th Cong., 1st Sess. (1977)	44
Hearings on Departments of Labor and Health, Education and Welfare and Related Agencies Appropriations for Fiscal 1980, before the Senate Committee on Appropriations, 96th Cong., 1st Sess. 490 (Fed. 8, 1979)	13c
25 Fed. Reg. 8595 (September 7, 1960)	11c
29 Fed. Reg. 37773 (October 24, 1974)	14c
35 Fed. Reg. 18385 (December 3, 1970)	11c
39 Fed. Reg. 3756 (January 29, 1974)	13c
39 Fed. Reg. 42748 (December 6, 1974)	72
41 Fed. Reg. 21402 (May 25, 1976)	74,8c,9c
41 Fed. Reg. 25059 (June 22, 1976)	1
41 Fed. Reg. 31860 (July 30, 1976)	11c
42 Fed. Reg. 18850 (April 8, 1977)	10c
42 Fed. Reg. 22516 (May 3, 1977)	11,12,16
42 Fed. Reg. 27452 (May 27, 1977)	7,12
42 Fed. Reg. 34289 (July 5, 1977)	11c
42 Fed. Reg. 54148 (October 4, 1977)	5,16,1c
43 Fed. Reg. 8808 (March 3, 1978)	10c
43 Fed. Reg. 21838 (May 19, 1978)	10c
43 Fed. Reg. 27350 (June 23, 1978)	31,59
43 Fed. Reg. 52952 (November 14, 1978)	31,14c
43 Fed. Reg. 54354 (November 21, 1978)	57,14c
44 Fed. Reg. 17070 (March 20, 1979)	10c
44 Fed. Reg. 39858 (July 6, 1979)	5c,6c

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Bolt, Baranack & Newman, Inc., *Economic Impact Analysis of Proposed Noise Control Regulation*, Rep. No.-3246, April 21, 1976	14c
THE BUDGET OF THE UNITED STATES GOVERNMENT—FISCAL YEAR 1980 (1979)	77
Carter, *Dispute Over Cancer Risk Quantification*, 203 SCIENCE 1324 (March 30, 1979)	81
COMPACT OXFORD ENGLISH DICTIONARY (1971)	41
Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693 (1977)	4c
Crump, *et al.*, *Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2793 (1976)	4c
Currie, "*OSHA*," 1976 AM. BAR FOUNDATION RESEARCH J. 1107 (1976)	37,38
FAA, *Establishment Criteria for Airport Traffic Control Towers*, Rep. No. ASP-75-4, (U.S. Dep't of Transp., Oct. 1975)	11c
FEDERAL RADIATION COUNCIL, BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS, Report No. 1 (May 1960)	11c
Interagency Regulatory Liaison Group, *Scientific Bases for Identifying Potential Carcinogens and Estimating Their Risks*, 44 Fed. Reg. 39858 (July 6, 1979)	5c,6c
Interagency Task Force on Workplace Safety and Health, MAKING PREVENTION PAY, THE FINAL REPORT OF THE INTERAGENCY TASK FORCE ON WORK-PLACE SAFETY AND HEALTH (1979)	73
Mantel & Schneiderman, *Estimating Safe Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH 1379 (1975)	4c

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NATIONAL ACADEMY OF SCIENCES, Decision Making For Regulating Chemicals in the Environment (1975)	2c,7c,8c
NATIONAL ACADEMY OF SCIENCES, Principles for Evaluating Chemicals in the Environment, (1975)	5c
NATIONAL BUREAU OF STANDARDS, MAXIMUM PERMISSIBLE AMOUNTS OF RADIOISOTOPES IN THE HUMAN BODY AND MAXIMUM PERMISSIBLE IN THE AIR AND WATER, WBS Handbook 69 (April 1959)	11c
NATIONAL RESEARCH COUNCIL, DRINKING WATER AND HEALTH (1977)	5c
NIOSH, SUSPECTED CARCINOGENS: A SUBFILE OF THE NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES, 2d Edition, Herbert E. Christiansen (Ed.) HEW Publication No. (NIOSH) 77-149 (December 1976)	4
OSHA PRESS RELEASE, USDL 78-625 (July 24, 1978)	5
OCCUPATIONAL SAFETY & HEALTH REPORTER (BNA) 1606 (March 20, 1979)	13c
OFFICE OF SCIENCE AND TECHNOLOGY POLICY, IDENTIFICATION, CHARACTERIZATION, AND CONTROL OF POTENTIAL HUMAN CARCINOGENS: A FRAMEWORK FOR FEDERAL DECISION-MAKING (Feb. 1, 1979)	6c
THE PRESIDENT'S REPORT ON OCCUPATIONAL SAFETY AND HEALTH (OSHA Annual Report 1974)	13c
U.S. Dep't of Labor, *Report to the Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies* (May 14, 1979)	12c
Vigliani, *Leukemia Associated with Benzene Exposure*, 271 ANN. N.Y. ACAD. SCI. 143 (1975)	8
WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 831 (1971)	41

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On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR RESPONDENTS

QUESTION PRESENTED

Whether the court below correctly set aside OSHA's[1] reduction of the benzene exposure standard from 10 parts per million ("ppm") to 1 ppm on the grounds that OSHA violated: (i) the standard-setting requirements of the Act, and (ii) the requirement that there be "substantial evidence" supporting OSHA's "determination" that a reduction to 1 ppm would produce "appreciable benefits."

[1] Sections 2(b)(3) and 6(b) of the Occupational Safety and Health Act ("Act" or "OSH Act") authorize the Secretary of

(footnote continued on next page)

COUNTERSTATEMENT OF THE CASE[2]

In an effort to portray the decision below as extreme and impractical, OSHA exaggerates the court's holding as requiring it to perform a mathematically-precise "cost-benefit" analysis. OSHA asserts that the court's decision would require it in every case to ascertain "the number of *lives* (and other health benefits) that the standard will save and determine whether their *value*" is "*commensurate*" with the control costs imposed. OSHA Br. 32, 35 (emphasis added). OSHA alludes to this supposed requirement of "cost-benefit" balancing in its "Question Presented" (*id* 2.) and repeatedly throughout its

(footnote continued from previous page)
Labor to set occupational safety and health standards. 29 U.S.C. §§ 651(b)(3) & 655(b). The Secretary has delegated this authority to the Assistant Secretary for Occupational Safety and Health, the head of the Occupational Safety and Health Administration ("OSHA"). 41 Fed. Reg. 25059 (June 22, 1976).

[2] This Brief adopts the abbreviations for references to the record and legislative history set forth at n.1 of the Brief for the Federal Parties ("OSHA Br."). The opinion of the court of appeals, *American Petroleum Institute* v. *OSHA*, is reported at 581 F.2d 493, and is reproduced at Pet. App. 1a-33a. The benzene standard and OSHA's accompanying explanation appear at 43 Fed. Reg. 5918-70, and are reproduced at Pet. App. 34a-252a.

The principal statutory provisions upon which this Brief relies are set forth in full in Addendum A. In addition, a chronological review of the legislative history of the standard-setting provisions of the Act is contained in Addendum B ("Add. B"), and Addendum C ("Add. C") briefly summarizes the practices of other federal health and safety agencies as they bear on the issues in this case.

Respondents concur in and support the separate brief filed today on the "dermal exposure" issue.

Brief.[3] But in fact OSHA's distorted reading finds little support in either the court's opinion or the record of this case.

The crux of the holding below is that the Act does not permit OSHA to disregard the evidence and act arbitrarily when "substantial evidence does not support" the agency's determination that the benefits of its action are "likely to be appreciable." Pet. App. 18a (581 F.2d at 503). In essence, the court ruled that OSHA failed to comply with the Act when it made its "appreciable benefits" determination based upon nothing more than a tautological assumption that "exposures to low levels of toxic materials would be safer than exposure to higher levels." *Id.* 18a (581 F.2d at 503). In the court's view, this "assumption" could not override the record evidence showing that the health benefits, if any, of OSHA's lowered standard were likely to be insignificant. *Id.* 19a (581 F.2d at 504).

To cure the agency's failure to base its standard on "substantial evidence of discernible benefits" (Pet. App. 18a (581 F.2d at 503)), the court required—not that OSHA "conduct an elaborate cost-benefit analysis"—but only that, as part of its decision-making process, OSHA consider a "rough but educated estimate[] of the extent of benefits expected from reducing the permissible exposure level from 10 ppm

[3] *See, e.g.*, OSHA Br. 22-23, 33-36, 38-42, 48-49, 51-52, 54-56, 60, 68, n. 55, 73.

to 1 ppm." *Id.* 17a, 21a (581 F.2d at 503, 504).[4] Without such "a rough but educated estimate" of the risks prevented (*i.e.*, the benefits), OSHA lacked "the required support" to show "reasonable necessity for the standard promulgated." *Id.* 21a (581 F.2d at 505).

The reasons why the law requires OSHA to follow such a process in setting standards are obvious. Benzene is only one of a great many potential occupational hazards posing vastly differing risks. Regarding the risk of cancer alone, the National Institute for Occupational Safety and Health ("NIOSH") has identified nearly 2,000 suspect occupational carcinogens,[5] and OSHA itself has targeted almost 300 "Category I" carcinogens for standards comparable

[4] The court's holding goes no further than, and perhaps not as far as, the regulatory practices of other federal health and safety agencies, including the Environmental Protection Agency, the Food and Drug Administration, the Nuclear Regulatory Commission, the National Highway Traffic Safety Administration, and, on occasion, even OSHA itself. *See* pp. 20, 29-30, 73-75, *infra;* Add. C 8c-14c, *infra*. Significantly, the President's Council on Wage and Price Stability recommended that OSHA follow a closely similar process in this very case. A. 124, 126, 129-31. *See* pp. 18-19, 20, *infra*.

[5] NIOSH has published a list of 2,415 potential occupational carcinogens, of which 1,905 substances "were selected on the basis of reported neoplastic or carcinogenic effects." NIOSH, SUSPECTED CARCINOGENS: A SUBFILE OF THE NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES, 2d Edition, Herbert E. Christiansen (Ed.), HEW Publication No. (NIOSH) 77-149 (December 1976). Apart from great differences in the levels and extent of worker exposure to these substances, their carcinogenic potency can vary by as much as a factor of one million. *See* Add. C 3c-4c, *infra*.

to the one at issue in this case.[6] It defies not only the law, but common sense as well, for OSHA to blind itself to these realities and, instead, to regulate each hazard it identifies simply by picking an exposure limit and then proving that those affected can bear the cost and still survive financially. Yet, this is precisely what OSHA did in the case of benzene. *See* pp. 17-18, 21-24, 31, *infra*.

Given the magnitude of the job ahead, now is no time for OSHA to "bury[ ] its head in the sand." A. 47. What is needed for benzene (and other substances) is for OSHA to assemble, consider, and evaluate *all* the available scientific data, including evidence on the degree of risk reduction (*i.e.*, the benefits) expected to result from more stringent regulation. For unless OSHA carefully and systematically evaluates all of the available evidence, those most adversely affected in the long run will be the workers (who will receive less overall health protection) and the public (which ultimately will bear the cost of needless regulations).

[6] *See* OSHA's *Proposed Rule for the Indentification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54148 (October 4, 1977) ("OSHA Proposed Cancer Policy"). Under these proposed regulations, toxic substances would be classified according to the evidence suggesting that they are carcinogens. *Id.* 54168-74. Each substance classified as a "Category I" carcinogen would automatically be the subject of what OSHA calls a "full blown" standard reducing exposure to the "lowest feasible level," regardless of any differences in the carcinogenic potency, extent of exposure, or costs of controlling the substance in question. *Id.* 54170-71. OSHA has tentatively concluded that 269 of the approximately 2000 substances on NIOSH's "Suspect Carcinogens" list are "Category I" carcinogens. *See* OSHA Press Release, USDL 78-625, July 14, 1978 and attached lists (Exh. 132 in OSHA Docket H-90). *See also* Add. C 2c-4c, *infra*.

A. Background of the Benzene Standard

Few chemicals are more common in industry or society than benzene. Although OSHA alludes to benzene's commercial significance (OSHA Br. 9 n. 8), it neglects to mention that benzene is naturally present in water supplies, animal and plant matter, many foods[7] and, most significantly, in crude oil, where it occurs in amounts from trace levels to more than one percent by liquid volume.[8]

Benzene first appeared as a commercial product in the early 1800's. Today, it is manufactured in the petroleum refining process (and to a lesser extent, in the coal-coking process) for use in the petrochemical industry and in the production of gasoline. Pet. App. 6a (581 F.2d at 497-98). Countless intermediate and final products, including most plastics, as well as artificial fibers and rubber, are derived from benzene. *Id.* 6a (581 F.2d at 498), 69a.

Because benzene has been exhaustively studied, far more is known about its health effects than most other chemicals.[9] Short-term exposure to high benzene concentrations (over 250 ppm) can result in

[7] Testimony of Dr. Herman Kraybill (National Cancer Institute) Exh. 84.B-18 app. at 2-3, Tr. 1176, 1192-94; Testimony of Edward Baier (NIOSH), Exh. 84.A at 7, Tr. 749-50; 1132; Mobil Research and Development Corp. Memorandum, Exh. 117.

[8] Testimony of American Petroleum Institute ("API") witness Harold A. Galloway, Exh. 115.A-4 at 2-3, 5-7, Tr. 1465; testimony of API witness R.J. Comeaux, Exh. 115.A-2 at 2-4.

[9] A single report by OSHA witness Dr. Bernard Goldstein contains nearly a thousand scientific literature references regarding the health effects of benzene. Goldstein, *A Critical Evaluation of Benzene Toxicity* (Exh. 43.B). Many additional references were cited by other witnesses or listed in OSHA's Federal Register notice. *See, e.g.*, Exh. 2.

"acute" reactions ranging from headache to rapid death at levels of about 20,000 ppm. Pet. App. 6a (581 F.2d at 498), 79a-80a. Long-term exposure to levels above the present 10 ppm standard can produce "chronic" toxicity, including bone marrow depression, aplastic anemia, pancytopenia and chromosomal changes. *Id.* 7a (581 F.2d at 498). OSHA's current 10 ppm standard, adopted in 1971 (29 C.F.R. § 1910.1000 Table Z-2), was addressed primarily to these non-malignant effects.[10]

For many years, there has been evidence (including unsystematic population studies and case

[10] Despite the finding of the court below that the benzene standard was clearly designed to deal with the leukemia hazard of benzene exposure (Pet. App. 9a, 22a-23a n. 26, (581 F.2d at 499, 505 n.26)), OSHA's lawyers make a belated effort here to suggest that the standard should be sustained on the basis of benzene's non-malignant effects. OSHA Br. 19-20, 21 n.25. The record, however, shows that such effects played no role in the development of OSHA's standard.

The opening sentence of OSHA's Federal Register notice acknowledges that "[t]his standard is based on a determination ... that the available scientific evidence establishes that employee exposure to benzene presents a cancer-hazard—specifically, the hazard of developing leukemia." Pet. App. 67a. From the outset of the OSHA hearings, leukemia—not the non-malignant effects of benzene—was clearly the issue. Not even indirectly did OSHA's proposal invite comment on other effects; instead, OSHA said its proposal was "based on" leukemia, and that it was *because* the current standard was based on other effects that it "does not ... provide protection now shown to be necessary." 42 Fed. Reg. 27452, 27466 (Exh. 4). Moreover, fresh reassessments of all the available evidence by NIOSH (in 1974) and the American Conference of Governmental Industrial Hygienists (in 1976) have reaffirmed that OSHA's 1971 10 ppm standard is more than adequate to protect against these non-malignant effects. Exhs. 2-3, 89.A.

reports dating back as far as 1897),[11] that exposure to high benzene concentrations (in excess of 100 ppm) can cause leukemia.[12] None of these studies or reports, however, associated benzene concentrations below 100 ppm with the development of leukemia.

Despite the reports linking high benzene concentrations with leukemia, major scientific reviews of the evidence accumulated through 1976 were nearly unanimous in finding no need to revise the existing 10 ppm standard. NIOSH's 1974 Criteria Document for benzene (Exh. 2-4) recommended a 10 ppm exposure limit, which NIOSH termed a "conservative limit" designed to "prevent all adverse effects

[11] Pet. App. 99a. Many scientists believed that high-level benzene exposure might be associated with leukemia even before adoption of the current 10 ppm standard in 1971. *See, e.g.*, Hunter (Exh. 2-74); Cronkite (Exh. 2-26); Malory (Exh. 2-9); Browning (Exh. 2-31); Tareef (Exh. 2-28).

[12] For example, Dr. Muzaffer Aksoy, a principal medical witness for OSHA at the hearings, reported a two-fold excess incidence of leukemia among workers employed in unhygienic and poorly-ventilated Turkish shoe shops where benzene exposures ranged from 150-650 ppm. Testimony of Dr. Muzaffer Aksoy, Exh. 60 at 4-5; Tr. 157, 185. Dr. Aksoy repeatedly conceded that he had not observed leukemia in workers exposed to benzene levels under 100 ppm. Tr. 189, 200, 202, 260.

Similarly, Dr. Enrico Vigliani reported a twenty-fold excess incidence of leukemia among Italian rotogravure workers exposed to benzene concentrations "between 200 and 400 ppm, with peaks up to 1,500 ppm," and among Italian shoe workers where "the concentration ranged from 25-600 ppm, but mostly around 200-500 ppm." Vigliani, *Leukemia Associated With Benzene Exposure*, 271 ANN. N.Y. ACAD. SCI. 143, 144-45 (1975) (Exh. 2-49).

including leukemia from benzene exposure."[13] NIOSH's view was later confirmed by the National Academy of Sciences.[14]

In the fall of 1976, the conclusion previously reached by NIOSH and the National Academy of Sciences was reaffirmed by the International Workshop on the Toxicology of Benzene, an international conference of experts which endorsed a 10 ppm exposure limit for the following reasons:

> The Workshop discussed but could not agree on whether there was a concentration below which there would be no leukaemogenic effect clearly attributable to benzene. *Despite this inability to exclude the possible induction of leukaemia at benzene exposures below 10 ppm, it was agreed that such a case would be a rare occurrence.*

Exh. 17 at 7 (emphasis added).

[13] Memorandum of Dr. Herbert E. Christiansen (NIOSH) (November 13, 1974) (Exh. 32.B). In 1976, NIOSH issued Revised Criteria which recommended that the OSHA standard be reduced. Exh. 2-5. NIOSH's revised recommendation, however, relied primarily on a series of University of North Carolina and Harvard epidemiologic studies (*id.* 1) which the National Academy of Sciences (Exh. 2-4 at 13), the authors of the studies (Exh. 161 at 2, Tr. 3114-15), and later OSHA itself (Pet. App. 112a), all found to be inconclusive. Indeed, OSHA itself refused two 1976 petitions, one by NIOSH based on its Revised Criteria (Exh. 2-6), and a second by the United Rubber Workers ("URW") (Exh. 2-42), requesting immediate reduction of the standard. OSHA denied the URW request outright (Exh. 2-43), and its only response to NIOSH was the publication of "voluntary guidelines recommending observance of a 1 ppm limit." Exh. 2-44.

[14] Exh. 2-4 at ii. This is the same 1976 report by the National Research Council (the principal operating agency of the National Academy of Sciences) that OSHA erroneously

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This conclusion of the International Workshop reflects the results of years of scientific investigation and practical experience. Although hundreds of thousands of workers and tens of millions of other persons, including motorists who purchase gasoline,[15] are and have been exposed to small amounts of benzene for many years, there is no evidence of an increased incidence of leukemia even among the workers (about 30,000, by OSHA's estimate)[16] who are exposed to benzene concentrations up to 10 ppm under the current standard. *See* pp. 13-17, *infra*.

B. The Proceedings Before OSHA

1. Misinterpretation of the Infante Study and issuance of an emergency temporary standard

It was on the basis of the April 1977 Infante Study[17] that OSHA set in motion the chain of events that ultimately brought the present controversy to this Court. The Infante Study found a five-fold

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characterizes as concluding that benzene "must be considered a carcinogen." OSHA Br. 11. Actually, the Academy concluded that benzene may be "relatively weak or no[t] leukemogenic" at all, particularly at low exposure levels, and could only conclude that it is a "suspect leukemogen." Exh. 2-4 at ii, iii.

[15] *See* Exhs. 93A., 93.G.1, 93.G.2 (service station exposure data). Gasoline contains, on the average, about 2% benzene. Pet. App. 69a.

[16] Arthur D. Little, Inc., *Economic Impact Statement for Benzene* 1-7 (May 1977) (Exh. 5). Arthur D. Little was OSHA's economic contractor for the Benzene Standard.

[17] Infante *et al., Leukemia Among Workers Exposed to Benzene* (April 28, 1977) (Exh. 40). Earlier drafts of the study, dated April 15 and 26, 1977, are contained in the record as Exhs. 2-7 & 2-51.

increase in leukemia deaths among workers exposed to benzene during the 1940's at two Pliofilm[18] plants in Akron and St. Mary's, Ohio.[19] Without even consulting the available exposure monitoring data, OSHA misinterpreted the Study as associating the excess incidence of leukemia with benzene exposures "generally below 25 ppm"[20] or even "significantly below . . . 10 ppm."[21]

Based on this misconception, OSHA, on April 29, 1977, issued an Emergency Temporary Standard ("ETS") for benzene under Section 6(c) of the Act. 29 U.S.C. § 655(c).[22] The ETS imposed a 1 ppm exposure limit (as well as numerous other requirements) without any indication that alternatives,

[18] Pliofilm was a type of plastic food-wrapping material manufactured until the 1960's. Exh. 115.B-6 at 5-6; Tr. 766.

[19] OSHA's lawyers suggest that the Infante Study may seriously understate the actual incidence of leukemia experienced by Pliofilm workers. OSHA Br. 15 n.17. However, Dr. Infante himself testified that none of the additional leukemia cases reported by Dr. Sakol were within the population of workers which he (Infante) studied. Tr. 769. If Infante had expanded his study to include these cases, the enlarged study population would also have included far more non-leukemia deaths. Nor would the fact that leukemia is not listed on a death certificate (even though it may be the real cause of death) lead to an understatement of the comparative mortality, since the mortality among the study population is compared to the mortality experience of the general population, which is also based on death certificates that would reflect a similar degree of underreporting. *See* Tr. 1401-02, 1446-47.

[20] Preamble to the Emergency Temporary Standard for Benzene, 42 Fed. Reg. 22516 (May 3, 1977) (Exh. 1).

[21] OSHA Opposition to Stay Pending Judicial Review of the ETS, API v. OSHA, No. 77-1973 (5th Cir., filed June 1, 1977). *See* API Post-Hearing Br. 24-25 (Exh. 217-33).

[22] The ETS was published in the Federal Register on May 3, 1977. 42 Fed. Reg. 22516 (Exh. 1).

either more or less stringent than 1 ppm, had ever been considered.[23]

The ETS never took effect. It was challenged by many of the respondents here and was stayed by the Courts of Appeals for the Fifth and District of Columbia Circuits.[24] In the meantime, pursuant to Section 6(c)(3) of the Act, 29 U.S.C. § 655(c)(3), OSHA proposed a permanent benzene standard, which was essentially identical to the ETS,[25] and held hearings on the proposal between July 19 and August 10, 1977.

At the hearings, OSHA's interpretation of the Infante Study was quickly shown to be seriously in error. Contrary to OSHA's initial view that the workers studied by Dr. Infante were exposed to less than 25 ppm benzene, the evidence and testimony established that they probably were exposed to average benzene concentrations of 100 ppm, with excursions (for as long as thirty minutes at a time) that

[23] In fact, OSHA never cited any basis for its original choice of 1 ppm. In issuing the ETS, OSHA claimed that the 1 ppm level was based on a feasibility investigation by Arthur D. Little, Inc. 42 Fed. Reg. at 22521. But this study really did nothing more than estimate the compliance costs for the emergency 1 ppm exposure standard *already selected by OSHA*. *See* Arthur D. Little, Inc., *Compliance Costs for Benzene Emergency Temporary Standard* 4 (May, 1977) (Exh. 5). ("The objective of this study was to assess the costs of compliance for the proposed emergency regulation").

[24] API, *et al.*, v. OSHA, *et al.*, No. 77-1973 (5th Cir., Orders dated May 19 and June 6, 1977); Industrial Union Dep't, AFL-CIO v. Bingham, 570 F.2d 965, 187 U.S. App. D.C. 56 (1977).

[25] Proposed Permanent Standard, 42 Fed. Reg. 27451, 27460-64 (May 27, 1977) (Exh. 4).

ranged as high as 1,000 ppm.[26] The authors of the Infante Study conceded these points,[27] and one of them testified that OSHA had gone "off the deep end" in interpreting the Study as demonstrating that "exposures generally below 25 ppm have already induced leukemia."[28]

Consequently, OSHA was ultimately forced to concede that the Infante Study did no more than "provide[] additional evidence supportive of earlier studies," and that these "positive studies," including the Infante Report, "involve[d] high exposure levels." Pet. App. 107a, 124a. When so interpreted, the Infante Study added nothing new to the evidence which OSHA and various scientific groups had previously found insufficient to justify changing the current 10 ppm standard.

2. The absence of excess leukemia from low-level benzene exposures

With OSHA's initial erroneous interpretation of the Infante Study refuted, the search for evidence linking low-level benzene exposures with the development of leukemia had to focus on other studies.

[26] The court below accepted "that exposure was probably around 100 ppm . . . [and occasionally] as high as several hundred parts per million." Pet. App. 8a n.13 (581 F.2d at 498 n.13). The voluminous record evidence on this issue is summarized in API Post-Hearing Br. 23-37 (Exh. 217-33); Post-Hearing Brief of the American Iron and Steel Institute ("AISI") 35-44 (Exh. 217-36).

[27] *E.g.*, Testimony of Dr. Infante and Ronald Young, Tr. 988-989, 995.

[28] Testimony of Ronald Young, Tr. 815-816. Dr. Infante and Edward J. Baier, Deputy Director of NIOSH, also rejected any such interpretation of the study. Tr. 1137-1140.

These studies, however, served only to confirm the absence of any discernible excess incidence of leukemia from benzene exposures below 100 ppm.

For example, it was shown that when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of leukemia found in the principal studies cited by OSHA (the reports of Drs. Infante, Aksoy and Vigliani) *ceased to occur.* Nowhere was this seen more clearly than in the workplaces studied by Dr. Infante. Studies by the University of North Carolina of persons who worked in the same two Pliofilm plants examined by Dr. Infante, but at a later time when benzene exposures probably averaged 35 ppm or less, failed to uncover any excess incidence of leukemia.[29] Precisely the same result occurred in the work environments studied by Drs. Aksoy and Vigliani.[30]

This evidence that low-level benzene exposures present no significant risk of leukemia was bolstered by a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations

[29] D. Andjelkovic *et al.*, *Mortality Study of Rubber Workers with Special Reference to Work Exposure—Goodyear Akron Plants* 49, Tables B-5, 13 (July 1976) (Exh. 187. B-13). *See* API Post-Hearing Br. 56-57 (Exh. 217-33).

[30] As noted by the court below (Pet. App. 8a n.13 (581 F.2d at 498 n.13)), both Drs. Aksoy and Vigliani reported no increased incidence of leukemia in the worker populations they studied once the use of solvents with high benzene content was halted. Pet. App. 100a-101a, 102a. The record shows that these substitute solvents were toluene and gasoline, containing up to 15 percent benzene, and that these solvents were used at a time when the permissible level of occupational exposure was 20 ppm in both Italy and Turkey. *See* API Post-Hearing Br. 61-65 (Exh. 217-33).

of benzene. Thus, the Thorpe Study of 38,000 European refinery workers, the Tabershaw/Cooper Study of 21,000 American refinery workers, and Stallones' Study of the mortality experience of 42,000 Shell Oil Company workers, all failed to uncover any excess incidence of leukemia among workers exposed to low concentrations of benzene.[31] These results were consistent with the findings of a long-term mortality study of the steel industry, which showed that coke oven and by-product facilities workers, exposed over the years to low concentrations of benzene, had not experienced any excess incidence of leukemia.[32]

To be sure, these negative studies had their methodological imperfections—imperfections which, for the most part, were acknowledged by their authors.[33] But, contrary to OSHA's suggestion (OSHA Br. 18 & n.19), the record shows that these shortcomings almost certainly did not conceal a significant leukemia problem among the worker populations studied. For example, statistical evaluations of Thorpe's data indicated strongly that neither the problem of incomplete follow-up[34] nor the possible "dilution" of the results by inclusion of unexposed workers[35] affected the validity of Thorpe's

[31] *See* API Post-Hearing Br. 65-75 (Exh. 217-33).

[32] *See* AISI Post-Hearing Br. 59-60 (Exh. 217-36). Individual steel company reports confirmed the results of this industry-wide study. *Id.* 60-62.

[33] *See* API Post-Hearing Br. 65-75 (Exh. 217-33) (citing testimony).

[34] *See* Testimony of Dr. Steven H. Lamm, Tr. 2663.

[35] *See* Thorpe Study 378 (Exh. 2-34). In addition, Dr. Robert Snyder testified that "using the most powerful statistical tools

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conclusions. The National Academy of Sciences' appraisal of the Thorpe Study is essentially the same.[36]

In sum, the record contains evidence associating high-level benzene exposures of 100 ppm or more with an excess incidence of leukemia. But the evidence also indicates that benzene exposures of 10 ppm or less are unlikely to lead to any leukemia *at all—i.e.*, there is evidence of a threshold or "safe" exposure level well in excess of 10 ppm for the leukemogenic effects of benzene.[37] OSHA rejected this position, relying on a regulatory "policy assumption" that there is no safe level for exposure to any carcinogen. Pet. App. 181a-186a.[38] The court below, with some misgivings, upheld OSHA on this point. Pet. App. 18a (581 F.2d at 503). But whether or not the available evidence established the existence of a

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available and concentrating on the most highly exposed population of workers, it was not possible to detect a greater incidence of leukemia [in the Thorpe Study] than in the population at large." Exh. 156-2 at 17.

[36] NAS Report ii (Exh. 2-4): "In spite of the inherent shortcomings of Thorpe's study, it does seem to indicate that there is not an outstandingly high incidence of leukemia in the workers studied."

[37] The empirical data on this point were bolstered by extensive biochemical and theoretical evidence for the existence of a threshold level for the production of benzene-related leukemia. *See* API Post-Hearing Br. 85-91 (Exh. 217-33); AISI Post-Hearing Br. 51-57, 66-71 (Exh. 217-36).

[38] OSHA's lawyers attempt to leave the misleading impression that OSHA made its "no safe level" determination for benzene on a *factual* basis. OSHA Br. 17-19 & nn.19, 21. Actually, that determination reflects little more than an irrebuttable policy presumption which OSHA applies to all carcinogens. *See* Preamble to the ETS, 42 Fed. Reg. at 22517 (Exh. 1); OSHA's Proposed Cancer Policy, 42 Fed. Reg. at 54165-67. Indeed, OSHA stressed at the outset of the benzene hearings that it knows of no evidentiary showing which could ever overcome its "no safe level" policy presumption. Testimony of Grover Wrenn, Tr. 50-52.

threshold for benzene-related leukemia, it clearly confirmed the conclusion of the International Workshop that leukemia from benzene exposure below 10 ppm "would be a rare occurrence." *See* p. 9, *supra*.

3. The absence of any evidence showing that the standard would produce material or appreciable benefits

With even OSHA's medical witnesses unable to identify any association between low-level benzene concentrations and an excess incidence of leukemia,[39] one might have expected that OSHA would at least have utilized well-recognized extrapolation techniques to estimate the leukemia risk at levels of 10 ppm and below. But this OSHA refused to do, or even to attempt to do. OSHA provided no explanation for this refusal in its final Federal Register notice, and, at the hearings, all it could offer was the observation of Grover Wrenn, then OSHA's Deputy Director for Health Standards, that "there is no *definitive* dose-response relationship which would allow one to estimate quantitatively the degree of health protection afforded" by the standard. Tr. 131 (emphasis added).

Although the estimated cost of the proposed standard was substantial—one billion dollars on a discounted-present-value basis, and possibly much more[40]—OSHA never asked its economic contractor,

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[39] *See* Testimony of Grover Wrenn, Tr. 131; testimony of Dr. Muzaffer Aksoy, Tr. 187-89, testimony of Dr. Bernard Goldstein, Tr. 365.

[40] This $1 billion cost estimate for OSHA's proposed standard was derived from the cost estimates of OSHA's economic contractor, A.D. Little. A. 41. A.D. Little's estimates however, were challenged as significantly understated by as much as $4 billion. A. 127-28; Exh. 115.A-9 at 30-41.

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Arthur D. Little, Inc., to consider alternatives to a 1 ppm standard or to develop information concerning the health benefits that the standard might achieve. Accordingly, A.D. Little only parroted OSHA's claim about the absence of a "precise dose-response relationship" (Exh. 5 at 3-5), and was itself unable to "attach any significance to the reduction in benzene levels" mandated by the standard. Tr. 516-17.[41]

In light of the substantial resources at stake, as well as the absence of any demonstrated leukemia risk below 100 ppm, the President's Council on Wage and Price Stability ("President's Council") urged OSHA to evaluate the record evidence more closely to learn more about the potential health benefits, if any, of a 1 ppm standard. As the President's Council explained:

> Since OSHA is faced with a finite quantity of society's resources, or maximum costs that can be allocated to worker safety and health in any industry, OSHA should pay serious attention to the development of standards which will deliver the maximum increment of worker safety and/or health from every dollar spent on compliance.

A. 126. Even though the President's Council expressly recognized that "an accurate calculation"

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A.D. Little was never asked to provide a cost estimate for OSHA's final standard, which differed in certain respects from the standard originally proposed. The court below referred to the standard as having a "one-half billion dollar price tag" (Pet. App. 18a (581 F.2d at 503))—which it apparently derived, not on a discounted-present-value basis, but simply by adding the engineering and first-year operating costs estimated by OSHA in the Federal Register. *Id.* 17a (581 F.2d at 503), 133a-136a. If one assumes a 10% discount rate and applies it to OSHA's cost estimates, the total cost of the final standard (on a discounted-present-value basis) is approximately $810 million.

[41] *But see* n.42, *infra*.

might not be possible, it urged OSHA to develop benefit estimates for the 1 ppm proposal and possible alternative standards, using "[v]arying assumptions about the dose-response relationship" to obtain "a range of estimates" that would be of considerable "aid [to] OSHA in setting the final standard." A. 130.

This recommendation was echoed by Dr. Richard Zeckhauser of Harvard's School of Public Health, who testified that such a "range of estimates" is essential if OSHA is to achieve "the maximum level of health protection for whatever level of resource expenditure that we make." A. 130, 137.[42]

Whatever contrary implication may emerge from OSHA's Brief, neither the President's Council nor Dr. Zeckhauser ever suggested that OSHA must place a dollar value on human life. Rather, they simply urged that OSHA regulate as intelligently as possible, using "full information so that people in authority ... can see what trade off[s] they are making." A. 42. If a standard will only "buy minuscule protection for an extra-ordinarily high amount," then "we will find that we have achieved less for health and safety than we could have." A. 48, 137.

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[42] Significantly, OSHA's own economic contractor, A.D. Little, testified that it was capable of performing the type of "cost-effectiveness" analysis called for by the President's Council and Dr. Zeckhauser. *See* Pet. App. 19a (581 F.2d at 504); Testimony of Dr. Lawrence Partridge, Tr. 512, 515, 518. OSHA, however, never asked A.D. Little to perform such an analysis. *See* p. 17-18, *supra*.

In asking for "full information," both the President's Council and Dr. Zeckhauser acknowledged the absence of "precise" data associating the dose (or exposure) with the response (excess leukemia). *See e.g.*, A. 130, 144, 159. But neither viewed the absence of a "precise" dose-response relationship as an excuse for OSHA's failure to do a better job. Dr. Zeckhauser testified that other federal health and safety agencies often develop a "broad range" or even a "maximum estimate of the benefits," and that such estimates "would be of immense value" to OSHA in evaluating its proposal. A. 54, 144. For "it is quite possible in this case that knowing the maximum benefit might tell us what we shouldn't do. It might tell us that this present decision is wrong." A. 54. *See generally* A. 42-45, 54-55, 82, 130, 144, 159; API Post-Hearing Brief at 92-93 (Exh. 217-33).

As a demonstration of how such an "upper-bound" estimate might be made, Dr. Richard Wilson, head of Harvard's Energy and Environmental Policy Center, provided OSHA with an analysis that incorporated a series of conservative assumptions designed to overstate the actual risks encountered in exposure to benzene. His analysis showed that the leukemia risk from benzene exposure at 10 ppm is exceedingly small—indeed, it is comparable to the cancer risk associated with such everyday activities as air travel or eating or drinking normal amounts of commonly available foods and liquids. A. 79-80, 174. *See* p. 76, *infra*. Overall, Dr. Wilson estimated that by reducing benzene exposures to 1 ppm, OSHA could expect to prevent, at most, one case of leukemia (and one other assumed case of cancer) every six years. A. 81.

Dr. Wilson's demonstration was soon supported by the results of an analysis prepared by the Environmental Protection Agency ("EPA"), assessing the risk of leukemia to the entire American population presented by ambient benzene concentrations in the parts per billion range. A. 15-29. Because of its obvious relevance, OSHA submitted EPA's demonstration to the court below, which was relied on in its decision. *See* Pet. App. 19a n.23 (581 F.2d at 504 n.23). When EPA's results were converted from an environmental context (with a population basis of 215 million people) to an occupational context (of 30,000 workers exposed below 10 ppm), its conclusions were shown to be virtually identical to those reached by Dr. Wilson. A. 30-33. If anything, EPA's assessment suggested that Dr. Wilson had been unnecessarily conservative in several respects, and that a more realistic estimate was that OSHA's 1 ppm standard would prevent, at most, only one case of leukemia every 15 to 38 years. A. 33-34.

C. OSHA's Determination of "Appreciable Benefits" in Support of the Final Standard

Even though it was forced to concede that the Infante Study, like the earlier reports, showed no association between benzene exposures of less than 100 ppm and the development of leukemia, OSHA retained a 1 ppm limit in its final standard. Despite all the attention that had been given at the hearings to the question of what, if any, additional health benefits might be achieved by reducing the present standard from 10 to 1 ppm, OSHA brushed the issue aside, devoting barely one page out of its lengthy 50-

page Federal Register notice to a discussion of the question. 43 Fed. Reg. at 5940-41. Pet. App. 158a-163a.

OSHA's Brief attempts to leave the erroneous impression that the evidence summarized above was squarely addressed and rejected on the grounds that "the lack of data made it impossible to quantify the health risk at various levels of exposure," and that such an analysis was, in any event, barred by Section 6(b)(5) of the Act. OSHA Br. 23. But, in fact, nowhere in OSHA's Federal Register notice is there a logical or meaningful discussion of these two issues. Nor does OSHA address the record evidence in a coherent and rational manner. All OSHA's Federal Register notice does is to "determine" that the benefits of a reduction to 1 ppm "are likely to be appreciable," without citing any supporting evidence.

To be sure, OSHA's Federal Register notice does begin by citing Section 6(b)(5) of the Act, which it says directs the Secretary "to set standards which attain the 'highest degree of health and safety protection for the employee." Pet. App. 159a. Nowhere does OSHA contend, however, that an estimate of benefits is prohibited by Section 6(b)(5). To the contrary, it asserts that "a systematic evaluation" of benefits as well as costs *"is to be encouraged." Id.* (emphasis added).

Having provided this inconclusive interpretation of the Act, OSHA then purports to address the record evidence concerning health benefits. It first asserts that "a *precise* quantitative relationship" between dose and response "cannot be established" for benzene. Pet. App. 160a (emphasis added). OSHA makes no mention, however, of the experience of virtually every other federal health and safety agency (or of the uncontradicted evidence in this case), demonstrating that rough but educated estimates can be made, and that such estimates would be "of immense value" in enlightening OSHA's decision—even in the absence of "precise" dose-response data.

Nor does the Federal Register notice provide a rational explanation for OSHA's decision to reject outright the risk demonstrations for benzene discussed above. Rather, OSHA simply announces that it is "unwilling to rely" on Dr. Wilson's estimates, citing no record evidence except the Infante Study. OSHA nowhere explains why the Infante Study, which, along with other studies relied on by OSHA, formed the basis for Dr. Wilson's extrapolation, should lead to rejection of Wilson's results—particularly in light of the confirmatory EPA assessment which relied exclusively upon Dr. Infante's data. Pet. App. 161a.

Perhaps most astounding of all is OSHA's "determin[ation]" that the benefits of its 1 ppm standard "are likely to be appreciable." Pet. App. 160a, 162a. OSHA makes this "determination" even though it admittedly made no attempt to evaluate the benefits of a 1 ppm standard (or any other alternative level). Not surprisingly, OSHA cites no supporting evidence for its "determination," even though all OSHA's "determinations" are required by law to be supported by "substantial evidence."

OSHA ends its "benefits" discussion in the same self-contradictory manner as it began. On the one hand, OSHA announces that "it may not substitute cost-benefit criteria for the legislatively determined directive of protecting all exposed employees" but, on the other hand, it claims (again without record support) that "the substantial costs" of its standard "are justified in light of the hazards of exposure to benzene." Pet. App. 163a.

D. The Decision of the Court Below Reversing OSHA's "Appreciable Benefits" Determination

The court below vacated OSHA's benzene standard in its entirety, finding that "substantial evidence does not support OSHA's conclusion that [the] benefits [of its standard] are likely to be appreciable." Pet. App. 18a (581 F.2d at 503).[43] In reaching this conclusion, the court reviewed the evidence of an association between high-level (greater than 100 ppm) benzene exposures and an excess incidence of leukemia. Pet. App. 6a-9a (581 F.2d at 498-99). It also summarized the results of years of scientific research and practical experience that failed to document any actual cases of leukemia from exposures below 100 ppm, and expressly noted OSHA's failure "to point to any empirical evidence documenting a leukemia risk at 10 ppm"—the level of the present standard. *Id.* 18a (581 F.2d 503).

[43] Because the standard was vacated in its entirety, the court below was not required to reach respondents' separate challenge to the various provisions that are supposedly ancillary to a 1 ppm exposure limit. Pet. App. 22a, 33a (581 F.2d at 505, 510). Even if the decision below were reversed, the case would have to be remanded to the Fifth Circuit for consideration of these additional issues.

The essence of the court's holding is that OSHA must do more than it did in *this* case to show that its 1 ppm benzene standard is reasonable and not arbirary.[44] Although OSHA had estimated what its standard would cost, it had made no effort whatsoever to look at the degree of risk prevented (and hence the benefits achieved) by reducing benzene exposures to 1 ppm. OSHA's failure to consider this question was considered inexcusable, particularly in light of the record evidence before the agency and the court showing that the benefits of the standard were likely to be exceedingly small. Pet. App. 19a n. 23 (581 F.2d at 504 n.23). Consequently, the court ruled that OSHA could not justify the reasonableness of a 1 ppm standard unless it did more than simply assume that the benefits resulting from a reduction to 1 ppm would be appreciable. Pet. App. 19a (581 F.2d at 504).

In reaching its decision, the court construed the Act as requiring that evidence on risks, benefits and costs play a part in OSHA standard-setting. In addition to the substantial evidence test of Section 6(f), the court relied on Sections 2(b), 3(8) and 6(b)(5) of the Act. The court cited approvingly respondents' argument that Section 2(b) requires OSHA to "assure maximum benefit from the finite amount industry can expend on safety and health." Pet. App. 14a (581 F.2d at 501). And it viewed

[44] Basically, the court envisioned a two-step process. First, OSHA must identify the approximate degree of risk prevented (*i.e.*, the benefits produced) by its standard. Pet. App. 18a-21a (581 F.2d at 503-05). Only when this first step has been completed is it appropriate to consider whether the estimated benefits bear any "reasonable relationship" to the costs imposed by the standard. *Id.* In this case, OSHA never completed the

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Section 3(8)'s "reasonably necessary" requirement as a concise statement of Congress' intent that OSHA issue more reasonable and better-supported standards than it did in this case. Pet. App. 13a-16a (581 F.2d at 501-03).

The court found compelling reasons for reversal in the "pragmatic limitations" of Section 6(b)(5). *Compare* OSHA Br. 31-32 *with* Pet. App. 15a-16a (581 F.2d at 502). In the court's words, Section 6(b)(5) "requires standards to be feasible and . . . contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards." Pet. App. 15a-16a (581 F.2d at 502). The court concluded that these "pragmatic" requirements—together with the non-absolute approach to regulation reflected in Sections 2(b) and 3(8)—deprive OSHA of "the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost." Pet. App. 15a (581 F.2d at 502).

Although the court construed the Act as requiring OSHA to consider the benefits of its actions as well as the costs, it cautioned that OSHA does not have to "conduct an elaborate cost-benefit analysis" in order to make the pragmatic judgment that the Act requires. Pet. App. 17a (581 F.2d 503). All the court required is that OSHA "regulate on the basis of knowledge rather than on the unknown," and that it "have some factual basis" for making "rough but educated estimates of the extent of benefits expected"—where, as here, such educated estimates are

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first step, *i.e.*, it failed "to provide an estimate of expected benefits from reducing the permissible exposure limit," thereby making it "impossible to assess the reasonableness of the relationship between expected costs and benefits." *Id.* 21a (581 F.2d at 504).

possible. Pet. App. 20a-21a (581 F.2d at 504).[45] Accordingly, affirmance of the decision below would not preclude OSHA from conducting further proceedings and adopting a revised benzene standard in accordance with the requirements of the Act.[46]

SUMMARY OF THE ARGUMENT

This case calls upon the Court to decide whether, in adopting occupational health standards, OSHA must: (i) attempt to identify the benefits (in the

[45] OSHA is also wrong when it says that the court considered such a "rough but educated" estimate to be "impossible." OSHA Br. 32. To the court, "impossibility" was only OSHA's "assertion," to be proved or disproved in any further proceeding that OSHA might choose to hold on benzene. Pet. App. 19a n.23 (581 F.2d at 504 n. 23). But it is hard to read the court as being anything but skeptical about OSHA's impossibility "assertion," since it noted that "preliminary assessments are now being made" (citing the EPA risk assessment), and that "OSHA's economic consultant testified that it could perform a cost-effectiveness analysis . . . which would have included some kind of risk quantification." *Id.* 19a n.23 (581 F.2d at 504 n.23). *See* pp. 17-21 & n. 42, *supra*.

Nor should OSHA read more into the expression "reasonable relationship" than the court did. Stripped to its essentials, the holding of the court required only that OSHA must consider evidence on both benefits and costs. Although the court referred to a "reasonable relationship" between the two, it gave no substantive content to that expression. What "reasonable relationship" meant to the court (other than OSHA's obligation to consider benefit and cost evidence and to explain how it exercised its discretion in light of such evidence) was never reached because the inadequate record before the court made it "impossible" to go further in this case. Pet. App. 21a (581 F.2d at 505).

[46] The court said as much when it noted that OSHA need not "wait until deaths occur . . . [before] it may validly promulgate a standard reducing the permissible exposure limit." *Id.* 20a (581 F.2d at 504). But whatever OSHA might be able to prove on a new record, the court held that "in *today's case* . . . Congress intended OSHA to regulate on the basis of more knowledge and fewer assumptions than *this record* reflects." *Id.* 21a (581 F.2d at 505) (emphasis added).

form of reduced health risks) that its standard is expected to achieve, and (ii) consider those benefits in light of the costs imposed by the standard. While OSHA concedes that this is a useful exercise that is performed under many health and safety statutes, it contends that the OSH Act is not an "ordinary statute." OSHA Br. 36. In OSHA's view, the OSH Act bars any consideration of these matters, with the sole exception that control costs may be taken into account if (and only if) the standard would drive entire industries or large numbers of employers out of business. Pet. App. 133a.

The OSH Act would have to be an extraordinary statute indeed if it condoned ignoring the kinds of evidence described above. But it is not such a statute. Unlike the Endangered Species Act of 1973, or the Delaney Clause of the Food, Drug, and Cosmetic Act, the OSH Act aims at relative rather than absolute protection. Throughout, its objectives and directives are stated in qualified rather than categorical language. And its legislative history confirms that Congress wanted OSHA to be pragmatic, setting safety and health standards that are reasonable and practical in light of all the evidence.

Other than repeating an out-of-context reading of a single sentence of the statute (OSHA Br. 36, 48, 55, 58), OSHA never attempts to explain Congress' use in the Act of such relative expressions as "feasible," "material," "adequate," "reasonably necessary" and "so far as possible." Yet it is hard to read these and other relative expressions as they are used in the Act without becoming convinced of Congress' pragmatic purpose. To be sure, Congress was concerned primarily with overall worker health and

safety. But that overriding goal can never be achieved unless OSHA seeks to allocate health and safety resources where they can be expected to do the most good. This pragmatic objective is antithetical to allocating enormous resources to prevent a *de minimis* health risk, as OSHA did here.

Congress realized that, in order to make informed and reasonable judgments about how workers can be best protected and how resources can be best allocated, OSHA would need to consider *all* of the available evidence. The Act spells this out in so many words in Section 6(b)(5). Specifically, standards must be based on "the best available evidence," including "research, demonstrations, experiments, and such other information as may be appropriate." Of special importance in this case is the further requirement that OSHA consider "the latest available scientific data in the field" and "experience gained under this and other health and safety laws."

The decision below requires no more (and in many instances, a good deal less) than what other federal health and safety agencies are already doing. These agencies, including the Environmental Protection Agency, the Food and Drug Administration, the Nuclear Regulatory Commission and the National Highway Traffic Safety Administration, all make what the court below called "rough but educated estimates" of the benefits of their respective health or safety standards. This approach has been endorsed by the President's Science Advisors and was recommended by the President's Council on Wage and Price Stability in this very case. Therefore, OSHA had a heavy burden to show, at a minimum, why it

could not do what is routinely being done by a host of federal health and safety agencies under "other health and safety laws."

OSHA cannot dispense with this and other requirements of the Act simply by defining "feasible" in such a way that the benefits of its standards become irrelevant and the control costs become a matter to be considered only if the standard in question threatens an industry's financial survival. This extreme stance defies not only common sense but also the legislative history. For what Congress wanted, as revealed by two separate amendments on the subject, was for OSHA to set reasonable and practical standards directed at "material" health hazards. As the evidence shows, that is not what OSHA did here.

In short, there are compelling reasons why the decision below should be affirmed. The court below was asked to uphold an enormously costly standard based upon nothing more than a scanty Federal Register notice that waffles back and forth between a poorly-articulated interpretation of the Act and a completely unsupported "appreciable" benefits "determination." This is precisely the type of arbitrary action that Congress intended to prevent when it subjected OSHA standards to the "substantial evidence" standard of review. If OSHA can rely upon a completely unsupported assumption to proclaim that the benefits of its standard "are likely to be appreciable" when the uncontradicted evidence shows the contrary to be true, then much of the Act, including the "substantial evidence" test, will have been drained of its intended meaning.

ARGUMENT

I. THE OSH ACT IS A PRAGMATIC STATUTE REQUIRING THAT OSHA USE THE "BEST AVAILABLE EVIDENCE," INCLUDING EVIDENCE ON RISKS, BENEFITS AND COSTS, TO SET "FEASIBLE" STANDARDS THAT ADDRESS "MATERIAL" WORKPLACE HAZARDS.

Stripped to its essentials, OSHA's position here reduces to the following: Once it determines that a substance is a carcinogen,[47] it *must* (subject to only one limitation) require that workplace exposure to the substance be eliminated *entirely*, to the extent that this can be accomplished by the use of existing technology or by technology that industry may develop in the future. The only limitation that OSHA would recognize is that its standard must not be so extraordinarily expensive that it would "drive entire industries or large numbers of employers out of business." Pet. App. 133a.[48]

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[47] Actually, OSHA takes the same position with respect to any toxic substance or harmful physical agent—carcinogenic or not—for which it believes no entirely safe level of exposure has been established. *See, e.g.*, Cotton Dust Standard, 43 Fed. Reg. 27350 (June 23, 1978); Lead Standard, 43 Fed. Reg. 52952 (November 14, 1978).

[48] *See, e.g.*, Cotton Dust Standard, 43 Fed. Reg. 27350, 27378 (June 23, 1978) ("[A]lthough some marginal employers may shut down, . . . the industry as a whole will not be threatened," so that "the productive capacity of the surviving firms . . . will be able to meet the demands for production of cotton products."); Lead Standard, 43 Fed. Reg. 52952, 52981-52983 (November 14, 1978) (While "some firms may choose to exit the market," the standard "assures economic viability" of, and will "not result in undue economic hardship on" the industries involved). *See also* text accompanying n.83 at *p. 60, infra.*

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According to OSHA, it is irrelevant that the present standard is already highly protective, that the risk (if any) from current exposures is exceedingly small, and that a further reduction to 1 ppm would produce only a minute reduction in an already small risk. Nor does OSHA acknowledge that the resources committed to controlling such small risks may be lost for other, more productive, health protection purposes. In short, OSHA deems benefits to be completely irrelevant and costs to be relevant only in the case of a possible industry shutdown. OSHA Br. 23, 48.

Common sense alone suggests that OSHA's interpretation goes too far. Surely, Congress did not intend industry, and ultimately the public, to expend vast sums at OSHA's command to eliminate even the most minuscule risk presented by a single substance so long as the industry could bear the cost and still survive. Nothing could frustrate the purpose of the OSH Act more completely than to have a grave or extraordinarily dangerous hazard go unregulated because the affected industry had already been driven to the limits of survival by the costs of controlling a far less serious risk addressed in a previous regulation. Yet this is the logical outgrowth of OSHA's

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OSHA's Brief takes the same position, *i.e.*, that the Act "leaves no room," and indeed "prohibits" taking benefits (and costs as related to benefits) into account in setting health standards. OSHA Br. 36, 38, 41, 48, 55, 32 n.33.

position, which takes account of costs only at the point of business collapse and which ignores benefits entirely.

Fortunately, there is a middle-ground where both costs and benefits are relevant and play a role in standard-setting. The Court need look no further than the Act and its legislative history to find this middle-ground. Indeed, once the focus expands from the selected portion of a single sentence of Section 6(b)(5)—upon which OSHA's case turns almost exclusively—it becomes clear that the Act as a whole requires consideration of risk, benefit and cost evidence in standard-setting.

As we show in Subpart A below, the starting point is the Act's overall purpose, Section 2(b), which expresses Congress' intent to provide—not the total elimination of individual hazards—but rather the most adequate protection against *all* health and safety hazards "so far as possible." This relative rather than absolute command is amplified in the definition of "occupational safety and health standard" (Section 3(8)), and is carried forward in the Act's standard-setting provisions (Section 6(b)).

In Subpart B, we focus specifically on the first sentence of Section 6(b)(5). As shown by the legislative history, the "feasibility" requirement there means that OSHA must demonstrate the "reasonableness" and "practicality" of its standards, taking account of all relevant considerations including risks, benefits, and costs. The requirement that OSHA consider evidence on risks and benefits is further underscored by the term "*material* impairment" which Congress substituted for an earlier version

("*any* impairment") in order to signify its intent that OSHA strive to eliminate "material" rather than inconsequential risks to workers.

Subpart C discusses the second and third sentences of Section 6(b)(5) and the "substantial evidence" review test of Section 6(f). Rather than permitting OSHA to rely on views, arguments and assumptions, the second and third sentences of Section 6(b)(5) require OSHA to develop standards on the basis of the "best available evidence"—including "research, demonstrations, experiments," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws." Together with the "substantial evidence" test of Section 6(f), these provisions define the evidentiary context within which OSHA must consider all relevant information, including that relating to risks, benefits and costs.

In Subpart D, we show that OSHA's inconsistent and poorly-articulated interpretation of the Act is entitled to no deference by the Court. On the contrary, if any interpretation is entitled to weight, it is that of the Occupational Safety and Health Review Commission, an independent adjudicatory tribunal established by Congress as a check on potential abuse by the Labor Department. The Review Commission has consistently rejected OSHA's extreme position and adopted a construction consistent with the decision below.

Finally, Subpart E examines the role the courts have given to consideration of risks, benefits and costs under similar safety and health legislation. In general, except where such consideration is clearly

and unequivocally precluded, the courts have interpreted terms such as those in the OSH Act to allow consideration of risks, benefits and costs.

A. The OSH Act Consistently Speaks in Terms of Relative Rather Than Absolute Protection, Thereby Necessitating Consideration of Risk, Benefit and Cost Evidence.

OSHA's case here rests almost exclusively on an out-of-context reading of the first sentence of Section 6(b)(5) as providing that health standards "shall . . . assure[ ] . . . that no employee will suffer . . . impairment of health." 29 U.S.C. § 655(b)(5). It is from these words that OSHA derives its interpretation that risks and benefits are irrelevant, and that costs are relevant only if the standard in question would "drive entire industries or large numbers of employers out of business." Any fair reading of the Act as a coherent whole refutes this absolutist interpretation.

The starting point for interpreting the Act is the statement of general purpose found in Section 2(b). That purpose is "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b) (emphasis added). In order to achieve this objective, OSHA must conscientiously consider the need to expend society's limited health resources wisely.

This relative objective of assuring overall protection "so far as possible" contrasts markedly with the far more absolute commands of other statutes, such as the controversial Delaney Clause of the Federal Food,

Drug, and Cosmetic Act.[49] Another example is the Endangered Species Act of 1973, recently construed by this Court in *Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978). In *TVA*, the Court interpreted the Endangered Species Act as barring the completion of the Tellico Dam on the Tennessee River because, in the words of the statute, construction of the dam would "*jeopardize* the continued existence" of an "*endangered species*" (the snail darter) or "*result* in the destruction or modification of habitat of such species." 437 U.S. at 160, 173 (emphasis in original).

The Court reached this result reluctantly, only after noting that Congress had carefully omitted language from Section 7 of the 1966 Act and in Section 2(b) of an Administration bill which would have limited the obligation of federal agencies to preserving "endangered species only '*insofar as is practicable and consistent with the*[*ir*] *primary purposes.*' " *Id.* 175, 181 (emphasis in original). Characterizing it as "very significant" that "the final version of the 1973 Act carefully omitted all of the reservations described above," the Court proceeded to hold that neither it nor the Interior Department was authorized to weigh "the loss of millions of unrecoverable dollars" against "the loss of the snail darter." *Id.* 182, 187.

The OSH Act, beginning with the statement of purpose, imposes no similar prohibition against a

[49] *See* 21 U.S.C. § 348(c)(3)(A). The Delaney Clause is a classic example of a statute providing absolute health protection. In contrast to the relative terms used throughout the OSH Act, the Delaney Clause provides simply and unequivocally that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." *See* pp. 38, 66, *infra*.

pragmatic and cost-effective allocation of society's resources. On the contrary, unless OSHA attempts to determine, at least roughly, what benefits each of its standards is likely to achieve, it will inevitably squander finite health protection resources on insignificant risks and frustrate the Act's overriding purpose of providing overall "safe and healthful working conditions" "so far as possible."

The relative rather than absolute protection intended by Congress is seen throughout the OSH Act. Section 2(b)(3) "authoriz[es] the Secretary of Labor to set mandatory occupational safety and health standards" which are, in turn, defined by Section 3(8) as "conditions . . . *reasonably necessary or appropriate* to provide *safe or healthful employment* and places of employment." 29 U.S.C. §§ 651(b)(3), 652(8) (emphasis added). When construed most reasonably, both the object of such standards ("safe or healthful employment") and the means of achieving it ("reasonably necessary" conditions) are seen to be relative in nature.

Long before the decision below, commentators interpreted Section 3(8) as a qualified rather than absolute definition. According to Professor Currie, Section 3(8) "does not simply require whatever is 'necessary' to achieve the requisite level of safety, it requires what is 'reasonably necessary or appropriate.' "[50] And "[w]hat is 'appropriate' may be what is desirable in light of feasibility or cost; what is 'reasonably necessary' may be what is both necessary and reasonable."[51]

[50] David P. Currie, "OSHA," 1976 Am. Bar Foundation Research J. 1107, 1134 (1976).

[51] *Id.*

Similarly, the words "safe or healthful," as Professor Currie points out, allow "room for some play."[52] Like the concept of a "safe" drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, the expression "safe or healthful" should be interpreted as seeking something less than perfection. As Judge Leventhal explained in *Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975, 993-94, 161 U.S. App. D.C. 395, 413-14 (1974), resolution of the issue of safety "inevitably means calculating whether the benefits which the drug produces outweigh the costs of its restricted use." *See also United States v. Rutherford*, 47 U.S.L.W. 4724, 4727 (June 19, 1979).

Like Sections 2(b) and 3(8), the standard-setting terms of Section 6 are qualified and relative.[53] Under the first sentence of Section 6(b)(5), individual health standards are to provide—not absolute protection—but instead only the "most adequate[ ]" protection against the health hazard to which the standard is directed. The requirements that protection be provided only "to the extent feasible" and

[52] *Id.*

[53] As one would expect, the objective of all three sections is the same. The first substantive criterion for a permanent standard issued under Section 6(b) is that it be designed "to serve the objectives of this chapter" (29 U.S.C. § 655(b)(1)) —*i.e.*, to provide protection against all occupational hazards "so far as possible." Likewise, whenever any permanent health or safety standard "differs substantially from an existing national consensus standard," OSHA must show that the permanent standard "will better effectuate the purposes of this chapter . . . ." 29 U.S.C. § 655(b)(8).

only against "material impairment" provide further pragmatic limitations, acknowledging the inevitable fact that there are some risks that it will not be "feasible" to eliminate, and others that must be disregarded as not "material," if workers are to receive the most adequate overall protection against all workplace hazards.

The second and third sentences of Section 6(b)(5), which apply to both health and safety standards,[54] contain further pragmatic limitations. By providing that standards be based upon "research, demonstrations [and] experiments," the second sentence amplifies the requirement that OSHA base its standards on "the best available evidence." Moreover, contrary to OSHA's implication (OSHA Br. 48), "the highest degree of health and safety protection for the employee" is but one of the "considerations" listed in the third sentence of Section 6(b)(5). Others include the "latest scientific data in the field," the "feasibility of the standards" and "experience gained under this and other health and safety laws."

Although OSHA is silent on the meaning of most of the expressions discussed above, its position appears to be that whatever Congress may have meant by relative expressions such as "so far as possible," "reasonably necessary," "adequately," "to the extent

[54] Under the Act, OSHA is authorized to set four types of occupational safety and health standards. The first two types, interim standards and emergency temporary standards, are governed by Sections 6(a) and 6(c), respectively. 29 U.S.C. § 655(a), (c). The remaining two types of occupational safety and health standards—permanent safety standards and permanent health standards, are governed by the provisions of Section 6(b), 29 U.S.C. § 655(b). *See* p. 50 n.70, *infra*.

feasible" and "material" is overridden by the use of supposedly absolute terms such as "no employee" in the first sentence of Section 6(b)(5). *E.g.*, OSHA Br. 36, 41-42, 48, 53. Yet, similar language elsewhere in the Act has been construed in a practical, rather than absolute manner by the courts.

For example, OSHA points to the so-called "general duty clause" of Section 5(a)(1) of the Act as an example of the Act's preference for absolute protection without regard to costs. OSHA Br. 52. That provision requires an employer to "furnish to *each* of his employees employment and a place of employment which are *free* from recognized hazards that are causing or are likely to cause death or serious physical harm . . . ." 29 U.S.C. § 654(a)(1) (emphasis added). The courts, however, have held that "Congress quite clearly did not intend the general duty clause to impose strict liability" even though the term "free" is concededly "unqualified and absolute." *National Realty and Construction Co. v. OSHRC*, 489 F.2d 1257, 1265-66, 160 U.S. App. D.C. 133, 141-42 (1973). Rather, the clause requires only "*demonstrably feasible*" measures that "*materially reduce*[ ]" the likelihood of harm. 489 F.2d at 1267, 160 U.S. App. D.C. at 143 (emphasis added).[55]

[55] *Accord*, Champlin Petroleum v. OSHRC, 593 F.2d 637, 640 (5th Cir. 1979) (Violation of the general duty clause had not been established because of "the lack of evidentiary support for the underlying assumptions" that the measures the employer failed to use "would materially reduce the hazard" involved.); Titanium Metals Corp. of America v. Usery, 579 F.2d 536 (9th Cir. 1978) (Because the OSH Act "was never designed, nor could it have been, to eliminate all occupational accidents," OSHA must demonstrate the "feasibility and likely utility" of protective measures in order to satisfy the general duty clause.).

In short, just as the expression "free" in the general duty clause should not be interpreted as "unqualified and absolute," so too the few words that OSHA relies upon must be tempered by Congress' use of relative expressions elsewhere in the first sentence of Section 6(b)(5) and throughout the Act. Acceptance of OSHA's construction would ignore these relative expressions and turn the OSH Act into an absolutist statute practically indistinguishable from the Endangered Species Act or the Delaney Clause of the Food, Drug, and Cosmetic Act. Congress clearly did not intend such a result.

B. Section 6(b)(5)'s Requirements That Health Standards Must Be "Feasible" and Must Address "Material" Health Hazards Necessarily Contemplate Consideration of Evidence on Risks, Benefits and Costs.

The key to OSHA's case, as previously noted, is the first sentence of Section 6(b)(5), which, OSHA says, "requires the Secretary to achieve the lowest possible risk" short of an industry shutdown. OSHA Br. 37.[56] In support of this position, OSHA claims that Congress "struck" a "compromise" that distinguished between health and safety hazards and applied "far

[56] OSHA bases this position not only upon what it views as the supposedly absolute language of the sentence discussed above, but also upon the word "feasible," which OSHA defines in strict dictionary terms as "capable of being achieved" or "done" with no further qualifications. OSHA Br. 38, 56. But the very definitions OSHA cites include pragmatic equivalents such as "practicable," "suitable" and "reasonable"—words far more liberal than OSHA's cramped interpretation of "feasibility" as any controls which can be implemented short of an industry shutdown. *See* I *Compact Oxford English Dictionary* 973 (1971); *Webster's Third New International Dictionary* 831 (1971).

more strict controls" to the former than the latter. *Id.* 37, 58-59. As we will show, OSHA's interpretation of the first sentence of Section 6(b)(5) collapses upon review of the legislative history.

1. **Addition of the words "feasible" and "material" was intended to assure that OSHA would adopt "reasonable" and "practical" health standards that do not squander vast resources on speculative or insignificant risks.**

From the outset of the legislative debate that produced the OSH Act,[57] Senator Javits was the key proponent of "feasible" standards. As the author of the original Administration bill (S. 2788), and the ranking minority member of the Senate Labor and Public Welfare Committee which considered the legislation, Senator Javits wanted standards to be "feasible" in the sense of being "reasonable" and "practical" as well as technologically achievable.

Senator Javits' original bill would have required an independent National Occupational Safety and Health Board[58] to submit any proposals for permanent standards "to the appropriate national standards-producing organization" for a report —which Senator Javits described as "a report on the

[57] Senator Javits described congressional consideration of the legislation as "the most bitter labor-management fight in years"—a fight which at times was "so bitter as to jeopardize the prospects for enactment of this bill during this session of Congress." Leg. Hist. 193, 194. Only after a series of compromises, summarized chronologically in Addendum B to this Brief, did the legislation pass both Houses.

[58] Consistent with the Administration approach, S.2778 vested standard-setting authority in an independent board, rather than in the Labor Department. S.2788 § 4(a), Leg. Hist. 36-37; Add. B 3b-4b, 8b-9b, *infra*.

feasibility of the proposed standards."[59] "Feasibility" for the purpose of such standard-setting was defined as including—"the *technical feasibility, reasonableness* and *practicality* of such standard."[60] This "feasibility report" was to be considered by the Board (along with other record evidence) in formulating its standards.[61]

The Senate Committee refused to go along with Senator Javits' proposal that occupational safety and health standards be set by an independent board, but agreed that "standards promulgated under Section 6(b) shall represent feasible requirements." Leg. Hist. 147. Accordingly, the term "feasibly" was added to Section 6(b)(5) by the Committee, thereby satisfying Senator Javits' concern that standards be reasonable and practical rather than "requir[ing] absolute health and safety protection in all cases . . . ." Leg. Hist. 197.[62]

[59] 115 Cong. Rec. 22517 (August 6, 1969).

[60] S.2788 § 4(c), Leg. Hist. 38-39 (emphasis added).

[61] *Id.* § 4(c)(2), (3), Leg. Hist. 39-40.

[62] *See* Add. B 8b-9b, *infra*. Without any citation to the OSH Act's legislative history on what "feasibility" was supposed to mean, OSHA argues that, in other statutes, Congress has distinguished between a feasibility requirement and a requirement that a cost-benefit analysis be performed. OSHA Br. 56 n.49. As previously discussed, however, the court below did not require a cost-benefit analysis in the sense OSHA uses that term. *See* pp. 2-5, 24-27, *supra*. Instead, OSHA need only take into account evidence on risks, benefits and costs, including "a rough but educated estimate" of benefits such as EPA and Dr. Wilson provided, or OSHA's economic contractor was capable of performing in this case. Pet. App. 19a n.23 (581 F.2d at 504 n.23). Because the court below did not go so far, there is no need to consider whether what OSHA says about these other statutes is correct.

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Even after the Senate Committee's inclusion of Senator Javits' "feasibility" amendment, many Senators were not satisfied. In pertinent part, the first sentence of Section 6(b)(5) then provided that "[t]he Secretary . . . shall set the standard which most adequately and *feasibly assures* . . . that no employee will suffer *any* impairment of health or functional capacity." Leg. Hist. 242 (emphasis added). This formulation was critized as "inherently confusing and unrealistic." Leg. Hist. 367.

First, the apparent prohibition against "any" impairment of health and "any" diminution of life expectancy was viewed as wholly impractical, since some risk was thought to be inherent in all employment. As Senator Dominick observed, "[n]o job can be rendered perfectly safe, and no employee can be

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One statute OSHA did not cite, the Federal Mine Safety and Health Act ("Mines Act"), 30 U.S.C.A. §§ 801 *et seq.* (Supp. 1979), helps to illustrate some of the differences between what the court below required and a cost-benefit analysis. The purpose of the Mines Act was to strengthen the Federal Coal Mine Health and Safety Act of 1970, which, in turn, was already far more stringent than the OSH Act. For example, the Coal Act required standards to assure "*to the greatest extent possible*" that no miner would suffer "*any disability*" (30 U.S.C. § 841(b) (1971) (emphasis added)) and contemplated that mines would be made "*as safe as present technology will permit.*" H. REP. NO. 91-563, 91st Cong., 1st Sess. 22, *reprinted in* [1969] U.S. Code Cong. & Ad. News 2524 (emphasis added).

To make the Coal Act even more stringent, the Mines Act deliberately dropped the expression "to the extent feasible" in the provision analogous to the first sentence of Section 6(b)(5) and adopted the more lenient "arbitrary and capricious" review standard. *See* 30 U.S.C.A. §§ 811(a)(6)(A), 811(d) (Supp. 1979); S. REP. NO. 95-312, 95th Cong., 1st Sess. 22, (1977). These changes were the result of Congress' concern about the "appallingly" and "unconscionably high" rate of injury and death among miners—"more than four times as great as the average for all manufacturing industries." S. REP. NO. 95-181, 95th Cong., 1st Sess. 7 (1977); H.R. REP. NO. 95-312, 95th Cong., 1st Sess. 3 (1977); 115 Cong. Rec. 2657 (daily ed., June 21, 1977).

rendered perfectly secure from injury," so that "[i]t is unrealistic to attempt, as this section apparently does, to establish a utopia free from hazards." Leg. Hist. 480.

Senator Saxbe pointed to the inevitable trade-off between employment and health, since "any type of exposure is going to affect" functional capacity and life expectancy. Leg. Hist. 338. Senator Dominick, citing examples of a bus or street car driver constantly exposed to risks of air pollution and traffic accidents (Leg. Hist. 423, 481), sought to eliminate any suggestion that health standards "must assure that there will not be any risk at all." Leg. Hist. 481. As Senator Dominick observed, "there is no way a criteria [sic] can be established so that an employee would not be faced with some risks for the period of his working life." *Id.* 481-82.[63]

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Reflecting the fact that feasibility was to play "a substantially less significant role" under the Mines Act (S. REP. NO. 181, 95th Cong., 1st Sess. 21 (1977)), the Senate voted down two proposed amendments which would have required an elaborate cost-benefit analysis before promulgating mine health or safety standards. *See* 123 Cong. Rec. S10218-S10224 (daily ed., June 20, 1977) and S10289-S10290(daily ed., June 21, 1977). But the legislative history shows that the fact that elaborate cost-benefit analyses do not have to be performed under the Mines Act does not relieve the Secretary of his obligation to consider risk, benefit and cost evidence. Specifically, the term "feasibility" (as it appears in the counterpart of the third sentence of Section 6(b)(5)) means "that the Secretary is required to indicate what his best estimate of the costs will be and of the benefits to workers." 123 Cong. Rec. S10290 (daily ed., June 21, 1977) (remarks of Senator Javits).

[63] Unless this and related problems were corrected by a more "balanced" bill, Senator Saxbe predicted health standards might amount to "harassing measures that would, in effect, limit production in areas that are not necessarily going to

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A second, closely-related concern was that the purpose of Senator Javits' "feasibility" amendment had not been given full effect in the Committee's bill. As Senator Dominick explained, the first sentence of Section 6(b)(5)

> could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or [diminished] life expectancy .... In addition, in many cases, the standard which most 'adequately' and 'feasibly' assures the elimination of the danger would be the prohibition of the occupation itself.

Leg. Hist. 367 (emphasis in original).

Neither Senator Williams, the floor leader of the Committee bill, nor any other Senator, expressed disagreement with these criticisms.[64] Senator Dominick initially proposed to drop the first sentence of Section 6(b)(5) altogether, but he soon laid aside an amendment to that effect in light of "modifications" that he was discussing with Senators Williams and Javits. Leg. Hist. 482. These "modifications," amending the first sentence of Section 6(b)(5) to its present form, easily passed the full Senate.

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increase safety." Leg. Hist. 320-21. If substantial resources had to be directed to eliminating such immaterial risks, the result, Saxbe feared, would not be "to make the plant safer ... but rather to make the business less competitive ...." *Id.* 321.

[64] The claim in OSHA's brief that supporters of the Senate Committee bill "embraced" these criticisms "as a description of their purpose" (OSHA Br. 37) is simply incorrect. Significantly, OSHA does not cite a single reference to the legislative history to prove its point.

In sum, addition of the word "feasible" to Section 6(b)(5) in the Javits and Dominick amendments was designed, in Senator Dominick's words, to assure that the Secretary would take only "such steps as are *feasible* and *practical*" to protect the health of employees. Leg. Hist. 502 (emphasis added). *See* Add. B 8b-9b, 13b-17b, *infra*. Likewise, the substitution of the term "*material* impairment" for the term "*any* impairment" was intended to prevent OSHA from regulating inconsequential health risks.[65] Taken together, the "feasibility" and "materiality" requirements of Section 6(b)(5) were intended to insure that OSHA would not waste vast resources in preventing immaterial risks through standards that are unreasonable and impractical.

2. Neither the Act nor its legislative history supports OSHA's portrayal of Senator Dominick's amendment as a "compromise" placing "more stringent controls" on health than on safety hazards.

Rather than address the real reasons for Senator Dominick's floor amendment,[66] OSHA would portray his changes as a "compromise," demonstrating that

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[65] While it is plausible, as a purely linguistic matter, to interpret this change as applying to the type of impairment involved, the legislative history shows that it was also intended to apply to the materiality of the risk. Add. B. 13b-18b, *infra*.

[66] None of the legislative history discussed above is anywhere mentioned by OSHA. Its Addendum is even less candid, claiming erroneously that "the only other modification" (apart from the specific reference to "toxic substances and harmful physical agents") was to shift, without explanation, from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible." OSHA Br. 7a n.2. OSHA never discusses the important statutory change from "any" to "material" impairment, nor Senator Dominick's explanation for why the "feasibility" provision needed to be changed. Leg. Hist. 367.

"Congress wanted toxic substances placed under controls far more strict than those applicable" to safety hazards. OSHA Br. 37, 58. This claim that Congress cared more about lives lost to disease than to accident is contrary not only to common sense[67] but also to the language of the Act and the legislative history.

The Act itself (Section 2(b)(6)) does no more than "recogni[ze] . . . the fact that occupational health standards present problems often *different* from those involved in occupational safety." 29 U.S.C. § 651(b)(6) (emphasis added).[68] Nowhere does it say that health standards are to be more stringent.

The legislative history confirms the congressional recognition that health (as opposed to safety) hazards present special problems of identification and correction that warrant additional legislative guidance.[69] But this additional guidance for identifying and treating health hazards did not include a directive for more stringent regulation. Nor was any "compromise" of safety intended.

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[67] Significantly, both the House and Senate Reports stressed that 14,500 workers were killed, and 2.2 million disabled annually, mostly as the result of industrial *accidents*. Leg. Hist. 142 (Senate Report); Leg. Hist. 844 (House Report).

[68] According to Section 2(b)(6), these "different" problems include the difficulty of "establishing causal connections" between occupational exposures and disease either because of some delay in the onset of the disease (latency), or because cumulative exposures are needed before harm occurs. *See* Section 2(b)(6), 29 U.S.C. § 651(b)(6); Add. B 1b-2b, *infra*.

[69] The House Committee on Education and Labor, for example, observed that in contrast to safety hazards, which are "often immediately apparent," "[d]iseases resulting from occupational health hazards may not become known until years of continuous exposure have elapsed." Leg. Hist. 853-54. *See* Add. B 5b-6b, 15b-17b, *infra*.

In fact, the provision that became the first sentence of Section 6(b)(5) originated in the House Committee well before the Senate evolved the present text of Section 6(b)(5). Add. B 5b-6b, *infra*. As explained by the House Report, such a provision was necessary because "the committee feels it is vital that when the Secretary sets an occupational *health* standard he do so on the basis of the best available professional evidence," including evidence pertaining to the different problems presented by "regular exposure" to chemicals "for the period of the [employee's] working life." Leg. Hist. 848 (emphasis added). In short, the first sentence of Section 6(b)(5) was limited to "health standards" well in advance of the Dominick amendment adding the word "material" and clarifying the "feasibility" requirement. *See* Add. B 15b-17b, *infra*.

To be sure, only the legislative history in the House, not the statutory text, expressly restricted the first sentence of Section 6(b)(5) to health hazards. As Senator Dominick explained, however, this lack of specific reference to "toxic substances and harmful physical agents" was one of the deficiencies his amendment was intended to cure:

> What we were trying to do in the bill—unfortunately, *we did not have the proper wording or the proper drafting*—was to say that when we are dealing with *toxic agents or physical agents*, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health and safety would not be affected.

Leg. Hist. 502 (emphases added).

Besides being contrary to Senator Dominick's explanation of his amendment as simply a drafting clarification, OSHA's claim that health standards are to be more stringent is fundamentally at odds with the text of Section 6(b)(5) itself. Thus, OSHA wrongly claims that "[s]tandards for hazards other than toxic substances and harmful physical agents are governed by other [unidentified] sections that lack the 'feasibility' phrase." OSHA Br. 58. But the plain wording of the Act makes the second and third sentences of Section 6(b)(5) applicable to *both* safety and health standards, and the third sentence specifically requires OSHA to consider the "feasibility" of standards.[70]

In short, "feasibility" is, as one would expect, a consideration that applies to all OSHA standards, whether addressed to illness resulting from exposure to toxic substances or to accidents caused by unsafe

[70] Unlike the first sentence of Section 6(b)(5), which applies only to "standards dealing with *toxic materials or harmful physical agents* under this subsection," the second and third sentences apply broadly to all "standards *under this subsection*"—*i.e.*, subsection (b) of Section 6, which prescribes how OSHA is to "promulgate . . . any occupational *safety or health* standard." 29 U.S.C. § 655(b) (emphasis added). This reading is confirmed not only by the third sentence (which refers to "health and *safety* protection"), but also by the legislative history. *See* Add. B 17b n.18, *infra*. If Congress had intended Section 6(b)(5) in its entirety to apply only to health standards, it would have used the term "paragraph" rather than "subsection," as other provisions of the Act show. *Compare* Sections 6(b)(6)(B) and 6(c)(3) (referring to actions taken "under this paragraph" and "in paragraph (2) of this subsection").

working conditions.[71] For each type of standard, the question that should properly be asked is whether the limits and conditions that OSHA proposes are "reasonable" and "practical" and provide real benefits to workers—not whether the affected industry can bear the costs and still survive. When the regulatory issue is framed in this manner, the relevance of evidence on risks, benefits and costs (such as the EPA and Wilson estimates) is undeniable.

C. OSHA Must Support Its Standards by "Substantial Evidence" after Consideration of the "Best Available" Evidence, Including "the Latest Available Scientific Data in the Field" and "Experience Gained Under This and Other Health and Safety Laws."

Although OSHA talks at length about the first sentence of Section 6(b)(5), its Brief and actions in this case effectively ignore the second and third sentences of that provision. But these two sentences are highly significant, since they embody Congress' commitment to setting standards on the basis of a specific evidentiary foundation, rather than on "views and arguments," as would have been permitted under the House Committee bill. This strong preference for standards based on evidence rather

[71] Accordingly, there is no merit to OSHA's contention that the decision below results in a "topsy-turvy" construction of the Act. OSHA Br. 58. Nor is there any substance to OSHA's argument that the decision below undercuts what it calls the "non-material impairment criterion" of Section 6(b)(5). OSHA Br. 38. There is no such absolute "criterion," for as we have already shown, Congress wanted to eliminate impairment of health *only* "to the extent feasible" and *only* if the risk of such impairment is "material." *See* pp. 38-40, 42-47, *supra*.

In addition, OSHA's claim that the variance provisions of the Act (29 U.S.C. § 655(d)) somehow make "the statute 'cost effective' " OSHA Br. 9 n.7. is completely beside the point. As OSHA itself implicitly concedes, the variance provisions have nothing to do with the "level of protection" to be provided by a

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than on theories and assumptions is buttressed by the Conference Committee's inclusion of the more rigorous "substantial evidence" review standard.

One of the most controversial features of the bill reported by the House Committee was a provision allowing the Secretary of Labor to establish occupational safety and health standards after notice-and-comment rulemaking and an informal hearing, based on "any evidence, data, views and arguments submitted in connection with the hearing . . . ."[72] This provision was sharply denounced by legislators in both houses, who warned against the "substantial financial impact" of allowing standards to be based on " 'views and arguments' rather than probative evidence." Leg. Hist. 884. *See* Add. B 3b-4b, 6b-7b, 12b, 18b, *infra*.[73]

The Senate Committee eventually resolved this concern by addition of the second and third sentences of Section 6(b)(5). These requirements, applicable to both safety and health standards,[74] provide as follows:

> Development of such standards *shall* be based on *research, demonstrations, experiments*, and such other information as may be appropriate. In addition to the attainment of the highest degree of health

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standard. *Id.* The most that can be said for this argument is that the variance provisions allow a few employers to find more "cost-effective" ways to achieve a level of production which —under OSHA's view of Section 6(b)(5)—may produce minimal benefits at enormous cost (regardless of how compliance is achieved).

[72] H. R. 16785 § 7, Leg. Hist. 728-30.

[73] For example, the dissenting views of minority members of the House Committee charged that there was "[n]o reason" for "this deviation from regular and fair procedures," and that under the Committee bill, "[t]he requirements that administrative decisions be based on facts and sound reasons mean little. . . ." Leg. Hist. 884. The strength of the House Committee minority was so great that their substitute bill, rather than the Committee's bill, eventually passed the full House. Add. B 18b, *infra*.

[74] *See* pp. 48-50 & n.70, *supra;* Add. B 17b, n.18, *infra*.

> and safety protection for the employee, other considerations shall be *the latest available scientific data in the field*, the *feasibility of the standards, and experience gained under this and other health and safety laws.*
> (emphasis added)

Congress could hardly have chosen language more clearly designed to insure that standards would be based on the best available factual evidence rather than on "views and arguments." Thus, the second sentence requires that OSHA standards be developed and based upon scientific information such as "research, demonstrations, [and] experiments." And the third sentence directs OSHA to utilize "the latest available scientific data in the field" as well as "experience gained under this and other health and safety laws." Clearly, these words contemplate that OSHA will give careful consideration to "demonstrations" such as those pertaining to risks and benefits, and to the "experience [of] other" health and safety agencies that have successfully used such techniques and demonstrations. *See* pp. 73-75, *infra*.

Even these requirements, however, did not fully allay the concerns of those who feared that the Secretary of Labor would impose arbitrary and unjustified burdens on employers. Add. B 3b-4b, 12b, 18b, *infra*. The crux of this concern was that, even though the Secretary was required to base his standards on factual evidence rather than "views and arguments," employers' judicial remedies were inadequate under the bills reported by the House and Senate Committees. As stated by Senator Cook, under the "arbitrary and capricious" test provided in those bills, "it will be very, very strange if they can

ever win a case." Leg. Hist. 343-44.[75] Indeed, this was one of the chief concerns that led the full House to reject the bill reported by the Committee and to pass a substitute bill which vested standard-setting authority in an independent board, based on formal rulemaking procedures with review under the "substantial evidence" test. Add. B 18b & n. 19, *infra*.

In Conference, the House finally withdrew its insistence on an independent standard-setting board, but only in return for retention of the more rigorous "substantial evidence" review test. This, it was believed, would protect against the possibility that the Secretary would regulate in an arbitrary and unfair manner. As summarized by Representative Steiger, the floor leader for the bill passed in the House:

> The Secretary's standard will only be sustained by the court if it is supported by 'substantial evidence on the record considered as a whole.' Thus, the Secretary must have a record on which to base his findings and to serve as the basis for judicial review. The act does not provide for an independent board for standard-setting as did the House bill. However, court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that the conference report should be adopted.

Leg. Hist. 1218.[76]

[75] *See also* Leg. Hist. 344 (remarks of Senator Cook) ("they are just not going to win any lawsuits"); Add. B 3b-4b, 12b, *infra*.

[76] The courts have accepted that the "substantial evidence" review standard established by Section 6(f) represents a legislative compromise. As the Fifth Circuit observed, Section 6(f)

> accommodated the Senate's desire for administrative convenience and flexibility by accepting informal

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Accordingly, the addition of the "substantial evidence" review test is another indication that Congress intended standards under the Act to be based and reviewed, to the maximum degree possible, on evidence rather than on theories and assumptions. Far from excluding evidence pertaining to risks, benefits and costs, these provisions mean that "demonstrations" regarding such matters, as well as the experience of "other health and safety" agencies with the underlying techniques, are directly relevant to determining whether standards, such as the benzene standard, satisfy the substantive criteria of Section 6(b)(5) and are consistent with the relative overall health and safety objectives of the Act.

D. OSHA's Halting and Confused "Interpretation" Is Entitled to No Deference by the Court, Especially in Light of the Contrary Construction of the Occupational Safety and Health Review Commission.

Having addressed few of the statutory terms and little of the legislative history discussed above, OSHA falls back to a plea that this Court should accord "substantial deference" to "the Secretary's consistent and well-articulated construction of the Act." OSHA Br. 73. But, in fact, OSHA's "construction"

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> rulemaking procedures, but placated House concern for protection of employers from arbitrary burdens imposed by a massive federal bureaucracy, but [sic: by] adopting the substantial evidence test for judicial review.

Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 128 (5th Cir. 1974), *citing* Associated Indus. of New York State, Inc. v. Department of Labor, 487 F.2d 342 (2d Cir. 1973).

has been neither "consistent," nor "well-articulated," nor even thoroughly-considered, and, as such, is entitled to no special weight. Moreover, it conflicts with the far more logical and faithful construction of the Act adopted by the Occupational Safety and Health Review Commission ("OSHRC" or "Review Commission") which Congress established as a check on abuses of power by OSHA. Add. B. 3b-4b, 12b-13b, 19b, *infra*.

As OSHA implicitly concedes, an agency's statutory interpretation is never entitled to unqualified deference by a reviewing court. This Court, and not OSHA, has the "ultimate responsibility to construe the language employed by Congress." *Zuber v. Allen*, 396 U.S. 168, 192-93 (1969).[77] Although an agency interpretation may, in some circumstances, be influential, the weight to be accorded depends upon

> the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control.

Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).[78]

[77] *Accord*, SEC v. Sloan, 436 U.S. 103, 118 (1978); ("[T]he existence of a prior administrative practice, even a well-explained one," does not relieve the Court of its "responsibility to determine whether that practice is consistent with the agency's statutory authority."). As this Court recently noted, many decisions in which it has "deferred" to agency interpretations have not been based on deference at all, but rather on the Court's "own 'analysis of the structure and legislative history' " of the statute involved. Adamo Wrecking Co. v. United States, 434 U.S. 275, 287 n.5 (1978), *quoting* Train v. NRDC 421 U.S. 60, 86 (1975).

[78] *See also* Adamo Wrecking Co. v. United States, *supra*, 434 U.S. at 287-88; SEC v. Sloan, *supra*, 436 U.S. at 118.

OSHA's present construction of the Act lacks the "power to persuade" in all relevant respects. For one thing, the agency has not articulated a long-standing and consistent interpretation of the statutory provisions at issue here. Indeed, not once in its entire eight-year history has OSHA ever attempted a comprehensive and integrated construction of Sections 2(b), 3(8) and 6 of the Act. Nor has it done so in the cryptic, self-contradictory Federal Register notice issued in this case. *See* pp. 21-24, *supra*.[79]

Moreover, OSHA itself hedges about claiming that its construction has been consistent (OSHA Br. 72-73), and for good reason. As elaborated in Addendum C, OSHA's principal spokesperson recently testified that "incremental cost-benefit analyses" are a "key factor" in OSHA's standard-setting. Add. C 12c-13c & n. 33, *infra*. And, in an attempt to justify its standards for lead and cotton-dust under Section 6(b)(5), OSHA purported to perform elaborate analyses of the health benefits (reduced blood-lead levels in the case of lead, reduced incidence of "byssinosis" in the case of cotton-dust) expected from various alternative exposure levels. *See* Add. C 11c-12c, 14c, *infra*. Indeed, in the case of lead, OSHA went so far as to claim that its analysis satisfied the requirements of the decision below in this case. 43 Fed. Reg. 54354, 54431 (Nov. 21, 1978).

The inconsistency and confusion that have marked OSHA's interpretation of the Act have carried over even into its Petition and Brief to this

[79] As this Court has repeatedly observed, when the "Court can only speculate as to the [agency's] reasons for reaching the conclusion that it did, [the interpretation] obviously lacks the 'power to persuade' " and should not be accorded deference. SEC v. Sloan, *supra*, 436 U.S. at 118. *See also* Federal Maritime Comm'n. v. Seatrain, Inc., 411 U.S. 726, 745 (1973); Investment Co. Inst. v. Camp, 401 U.S. 617, 626-27 (1971).

Court. While OSHA's principal theme is that consideration of benefits and cost evidence is precluded by the Act, a far different position is suggested in the footnotes.

For example, both OSHA's Petition and Brief state in footnotes that: (i) use of risk assessment and cost-effectiveness techniques provides "very valuable" information regarding the costs of achieving various levels of health protection benefits (OSHA Br. 67 n.55); (ii) consistent with the Act, OSHA takes "the relative costs and benefits of the existing standards and the proposed standards into account" to "set priorities in the use of [its] own time and resources" (*id.* at 55 n.47); (iii) the Act permits OSHA to consider relative costs and benefits in deciding whether to propose a new standard for a toxic substance (OSHA Pet. 17 n.10); and (iv) risk assessments can and have been used in regulating non-carcinogens (OSHA Br. 67 n.55).

In light of these concessions, it is difficult to understand what is left of OSHA's case. To be sure, OSHA struggles valiantly to propose distinctions that would salvage its claim to a "consistent and well-articulated" interpretation of the Act. But the effort is wholly unconvincing. For example, it is hardly credible that Congress could have intended that information on relative costs and benefits—data that OSHA concedes are "very valuable" (*id.* 67 n.55)—may be taken into account to set priorities in the allocation of *OSHA's* resources (*id.* 55 n.47) but must be disregarded in deciding how to allocate the *societal* resources that are consumed by OSHA's standards.

Equally illogical is the notion that relative costs and benefits may be considered in deciding whether or not to adopt a new standard, but must be ignored in deciding what level of protection that standard should provide. OSHA Pet. 17 n.10; OSHA Br. 70-71. This is surely a distinction without a difference. Since the existing benzene standard limits exposure to 10 ppm, while the new standard would limit exposures to 1 ppm, the decision regarding the level of protection in the new standard is, in effect, a decision on whether or not to adopt a new standard at all.

By the same token, the distinction that OSHA seeks to draw between carcinogens and non-carcinogens has no basis in the Act. Nothing in Section 6(b)(5)—which applies to all toxic substances, carcinogenic and otherwise—indicates that risk and benefit evidence may be considered only in the case of non-carcinogens. The premise upon which OSHA's distinction rests is that there is "no safe level" for exposure to a carcinogen. OSHA Br. 67 n.55. But OSHA has taken the same "no safe level" position for non-carcinogens as well (*see, e.g.*, 43 Fed. Reg. 27350 (June 23, 1978) (cotton dust)) thereby rendering spurious the distinction upon which OSHA relies.

Moreover, any deference that might otherwise be due to OSHA's interpretation would be substantially undercut by the Review Commission's rejection of OSHA's extreme reading of the Act.[80] In the leading

[80] This Court has recognized that less deference is due to an agency interpretation of a statute where other agencies having responsibilities for administering the legislation have adopted a contrary view. *See* FCC v. American Broadcasting Co., 347 U.S. 284, 294-95 (1953) (The Court refused to adopt the FCC's definition of a statutory term where other affected agencies disagreed.).

case, *Continental Can Company*,[81] the Commission held that, in order "to effectuate the Congressional purposes underlying the Act," an OSHA noise standard requiring the installation of "feasible" engineering controls could be sustained only if the term "feasible" is applied so that "all the relevant costs and benefit factors [are] weighed."[82] OSHA had argued there, as it does here, that Section 6(b)(5) "requires employers to expend funds for each and every health hazard whether life threatening or not without limit so long as the expenditures for each hazard can be borne without putting the employers' financial condition in jeopardy."[83] The Review Commission rejected OSHA's position as "inconsistent with the intent of Congress," saying:

> Clearly, employers have finite resources available for use to abate health hazards. And just as clearly if they are to be made to spend without limit for abatement of this hazard their financial ability to abate other hazards, including life threatening hazards, is reduced.[84]

Accordingly, the Review Commission ruled that health standards must reflect a "priority for allocation of resources," so that worker health is maximized. The only way to accomplish this, the Commission held, is to consider "the costs which must be

[81] 4 BNA OSHC 1541, 1976-1977 CCH OSHD ¶ 21,009 (1976).

[82] 4 BNA OSHC at 1546-47, 1976-1977 CCH OSHD ¶ 21,009 at 25,255-56.

[83] 4 BNA OSHC at 1547, 1976-1977 CCH OSHD ¶ 21,009 at 25,256. *See* p. 31, *supra*.

[84] *Id.* The Commission added that, under OSHA's approach, "in some if not many cases [available resources] will be reduced to the point that [employers] will be put in financial jeopardy" in responding to other, more serious hazards. *Id.*

incurred and the benefits they will achieve."[85] This construction of the Act—which applies to *all* "toxic materials and harmful physical agents"—has since been consistently followed by the Commission.[86]

If deference is to be accorded to any administrative interpretation of the Act, the Review Commission's more logical and faithful view is entitled to greater regard than the inconsistent construction advanced by OSHA. This is particularly so since the Review Commission was purposely established by Congress as an independent agency with expertise comparable to OSHA's[87]—so that it could interpret

[85] *Id.*

[86] *See* Castle & Cooke Foods, a Div. of Castle & Cooke, Inc., 5 BNA OSHC 1435 1977-1978 CCH OSHD ¶ 21,854 (1977), *appeal docketed*, No. 77-2565 (9th Cir. July 14, 1977); Great Falls Tribune Co., 5 BNA OSHC 1433 1977-1978 CCH OSHD ¶ 21,844 (1977), *appeal docketed*, No. 77-2566 (9th Cir. July 14, 1977); West Point Pepperell, Inc., 5 BNA OSHC 1257, 1977-1978 CCH OSHD ¶ 21,751 (1977), *aff'd*, Marshall v. West Point Pepperell, Inc., 588 F.2d 979 (5th Cir. 1979); KLI, Inc., 6 BNA OSHC 1097 1977-1978 CCH OSHD ¶ (1977). *See also* n. 90 *infra*.

In only two cases has the Review Commission failed to apply the *Contental Can* rationale. The Commission's refusal in each case was based on the employer's failure to raise the issue. Both of these cases were reversed by the courts of appeals. Turner Co., Div. of Olin Corp., 4 BNA OSHC 1554, 1976-1977 CCH OSHD ¶ 21,023 (1976), *rev'd*, Turner Co. v. Secretary of Labor, 561 F.2d 82 (7th Cir. 1977); RMI Co., 6 BNA OSHC 1523, 1978 CCH OSHD ¶ 22,674 (1978), *rev'd*, RMI Co. v. Secretary of Labor, 594 F.2d 566 (6th Cir. 1979).

[87] Section 12(a) of the Act requires that the Commission be composed of three members who are "qualified" "by reason of training, education, or experience." 29 U.S.C. § 661(a). The courts have recognized the Review Commission's special expertise on occupational safety and health matters. *See, e.g.*, Southern Ry. v. OSHRC, 539 F.2d 335, 337-38 (4th Cir.), *cert. denied*, 429 U.S. 999 (1976).

the Act[88] and rule on the statutory validity of standards in the context of enforcement proceedings.[89]

Significantly, the Review Commission's construction has been upheld by the courts. For example, in *Turner Co. v. Secretary of Labor*, 561 F.2d 82 (1977), the Seventh Circuit adopted the Review Commission's *Continental Can* rationale in another noise case where OSHA interpreted the standard as requiring the use of expensive engineering controls instead of personal protective equipment (earplugs). The Court found that, after "thorough consideration of the . . . legislative history," the Review Commission in *Continental Can* had given the term "feasible" a construction that "is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act." 561 F.2d at 83, 85. Accordingly, the Court ruled that the "Commission must . . . determine whether the health benefits to employees who are already equipped with personal protection equipment justify the $30,000 cost to Turner for engineering controls."[90]

[88] International Union (UAW) v. OSHRC, 557 F.2d 607, 611 (7th Cir. 1977); Atlantic & Gulf Stevedores, Inc. v. OSHRC, 534 F.2d 541, 550-51 (3d Cir. 1976); Brennan v. Giles & Cotting, Inc., 504 F.2d 1255, 1261-62 (4th Cir. 1974). As the courts and commentators have pointed out, giving OSHA the sole administrative responsibility to interpret the Act would emasculate OSHRC's adjudicatory powers. *See* Currie, *supra* n.50 at 1119; Brennan v. Giles & Cotting, Inc., *supra*, 504 F.2d at 1261-62.

[89] Atlantic & Gulf Stevedores, Inc. v. OSHRC, *supra*, 534 F.2d at 550-51.

[90] 581 F.2d at 86. The Fifth Circuit observed recently that the interpretation of "feasible" adopted by the Review Commission in *Continental Can* and approved by the Seventh Circuit in *Turner* "certainly comports with the plain import of the term." Marshall v. West Point Pepperell, Inc., 588 F.2d 979, 981 n.3 (5th Cir. 1979).

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More recently, in *RMI Co. v. Secretary of Labor*, 594 F.2d 566 (1979), the Sixth Circuit approved what it called a "cost-benefit analytical framework for determining the economic feasibility" of a standard. *Id.* 568. Relying on "Congressional intent derived both from the statutory scheme and language and legislative history of the Act," the court, adopting the Review Commission's *Continental Can* rationale, held that "the costs of the proposed controls [are] to be balanced against the proposed benefits flowing therefrom in order *that resources [will] be allocated in priority to the degree of harm established.*" *Id.* 572 (emphasis added).

In sum, there is no basis here for deferring to OSHA's latest construction of the Act. Neither the agency nor its lawyers have presented the Court with the sort of "thorough," "validly reasoned" and "consistent" construction that has "the power to persuade." *Skidmore v. Swift & Co.*, *supra*. Furthermore,

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OSHA claims that *Turner* does not apply to "non-life-threatening health hazards." OSHA Br. 42 n.35. But the reference in the *Turner* opinion upon which OSHA's claim rests (581 F.2d at 86) does not so limit the decision. Moreover, the Review Commission and OSHA itself consider noise exposure—the health hazard involved in *Turner*—to be a "harmful physical agent," which, like benzene, is governed by § 6(b)(5) of the Act. *See Continental Can*, *supra*, 1976-1977 CCH OSHD at 25255-56.

Furthermore, the Review Commission has applied its *Continental Can* rationale to standards which beyond any question involve life-threatening hazards. *See, e.g.*, Republic Granite Co., Inc., 4 BNA OSHC 1711, 1976-1977 CCH OSHD ¶ 21, 167 (1976) (silica dust); Worley Brothers Granite Co., 4 BNA OSHC 2042 (1977) (same). Indeed, a Review Commission administrative law judge recently applied *Continental Can* in vacating an OSHA citation for a "serious" violation of the current 10 ppm benzene standard. Texaco Inc. and Oil, Chemical & Atomic Workers Union, 1978 CCH OSHD. ¶ 23,068 (1978) (OSHRC review pending). Further, the Sixth Circuit's decision in *RMI*, which reaffirmed *Turner*, relied on the decision below and other cases involving life-threatening hazards. 594 F.2d at 571-72.

the extreme reading of the Act advanced by OSHA's lawyers here has been rejected consistently by the Review Commission, whose more reasonable interpretation has been sustained by the courts.

E. OSHA's Reading of the Act to Preclude Consideration of Risk, Benefit and Cost Evidence Is Inconsistent with the Weight of Relevant Precedent.

While the precise issues and arguments before the Court have not been raised or addressed elsewhere, the relevant case law lends more support to respondents' interpretation than it does to the extreme construction advanced by OSHA. Thus, the holdings of the Seventh Circuit in the *Turner* case and the Sixth Circuit in the *RMI* case are consistent with the decision below. Other courts, although not addressing the issue so directly, have taken a similar position.[91]

OSHA relies on other decisions—most notably *Industrial Union Dep't, AFL-CIO ("IUD") v. Hodgson*, 499 F.2d 467, 162 U.S. App. D.C. 331 (1974), *Society of the Plastics Industry ("SPI") v. OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975), and *American Iron and Steel Institute ("AISI") v.*

[91] In Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 130 (5th Cir. 1974), the court stated: "The promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry." Similarly, stressing that "the rule to be applied is one of reasonableness and feasibility," the Eighth Circuit, in United Parcel Service of Ohio, Inc. v. OSHRC, 570 F.2d 806, 812 (1978), overturned an order enforcing a safety standard because of the failure "to give consideration to less rigorous requirements" having less severe economic consequences.

OSHA, 577 F.2d 825 (3d Cir. 1978), *petitions for cert. pending*, 47 U.S.L.W. 3422 (U.S. Dec. 8, 1978) (Nos. 78-918 & 78-919)—which, as the court below noted, involved their own factual records. Pet. App. 21a (581 F.2d at 505). Whether or not these cases are consistent with the holding of the court below,[92] the fact is that the *IUD*, *SPI* and *AISI* courts were not called upon, as this Court is, to provide a coherent interpretation of the Act as an integrated whole, giving meaning to all of the relevant provisions.[93]

Moreover, looking beyond the cases interpreting the OSH Act, decisions construing closely similar health and safety legislation provide strong support for rejecting OSHA's arguments here.

One example is the Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§2051, *et seq.*, which authorizes the adoption of consumer product safety rules that are "reasonably necessary to eliminate or reduce an unreasonable risk of injury."[94] This provision, as noted by the court below, has been construed to require the Consumer Product Safety Commission "to assess the expected benefits in light of the burdens to be imposed by the standard."[95] Since occupational

[92] For example, the court in *IUD* recognized that considerations apart from mere technological and financial capability—*e.g.*, the inpact on intra- and inter-industry competition—are relevant to determining whether a standard is "feasible" within the meaning of Section 6(b)(5). *See* 499 F.2d at 478.

[93] A good example of another statute so construed is this Court's recent decision in Southeastern Community College v. Davis, 47 U.S.L.W. 4689 (June 11, 1979).

[94] 15 U.S.C. § 2058(c)(2)(A).

[95] Pet. App. 17a (581 F.2d at 503), *citing* Aqua Slide 'N' Dive Corp. v. CPSC, 569 F.2d 831, 844 (5th Cir. 1978); D.D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978).

safety and health standards also must be "reasonably necessary or appropriate to provide safe or healthful employment," 29 U.S.C. § 652(8), it is reasonable to conclude that Congress intended to impose a similar obligation upon OSHA.

OSHA quarrels with this analysis principally on the ground that the CPSA "permits regulation only of risks that are 'unreasonable'" (*i.e.*, where the trade-off between the risks and utility of a product argue in favor of control), while, in OSHA's view, the OSH Act calls for the elimination of all hazards, no matter how trivial the risk or how great the cost of control. OSHA Br. 46-47. But OSHA's purported distinction is invalid. The goal of safe and healthful workplaces under the OSH Act—like the concept of a "safe" drug under the Food, Drug, and Cosmetic Act—is itself a relative objective, comparable to the CPSA's goal of eliminating unreasonable risks. *See* pp. 35-38, *supra*. As in the case of consumer product safety rules, trade-offs are involved whenever OSHA allocates substantial resources to the reduction of one health and safety risk, leaving fewer resources to be devoted to the reduction of other workplace hazards.[96]

[96] OSHA also attempts to distinguish the OSH Act from the CPSA on the ground that the "reasonably necessary" language in the former appears "in a collateral definition" rather than "in the clause granting the power to regulate." OSHA Br. 46-47. This argument was properly rejected by the court below (Pet. App. 14a-15a (581 F.2d at 501-02)), since there is no logical reason why placement of the phrase in one provision of the Act rather than another makes any substantive difference. *See, e.g.*, Walling v. Portland Terminal Co., 330 U.S. 148 (1947) (definition of "employees" in Fair Labor Standards Act held to be determinative of the question of the agency's substantive authority).

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Absent an express bar, other health and safety statutes also have been read to require a consideration of risk, benefit and cost evidence. For example, the National Highway Traffic Safety Act provides for the adoption of "reasonable, practicable and appropriate" traffic safety standards.[97] This provision has been construed as requiring the Secretary of Transportation to "identif[y] some of the costs associated with the proposal and determine[] that these costs are overriden by reasonably predictable benefits."[98] Similarly, the Federal Water Pollution Control Act provision directing that EPA's 1983 effluent limitation guidelines reflect "the best available technology *economically achievable* . . . which will result in *reasonable further progress* toward the national goal of eliminating the discharge of all pollutants,"[99] has been held to require consideration by

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OSHA also attempts to read Section 3(8) as if it were as broad as the "Necessary and Proper" Clause in the Constitution, citing cases which OSHA claims support an interpretation of Section 3(8) as allowing "the Secretary to issue any standard that he rationally concludes is appropriate." OSHA Br. 46. But none of the cases cited by OSHA involve statutes which contain the expression "reasonably necessary." Where Congress has used that language, as in CPSA, it has been construed in a manner consistent with the decision below. *See* p. 66 & n. 95, *supra*.

[97] 15 U.S.C. § 1392(f)(3).

[98] H & H Tire Co. v. Department of Transportation, 471 F.2d 350, 356-57 (7th Cir. 1972) (Stevens, J., concurring opinion adopted by the court) (footnotes omitted).

[99] 33 U.S.C. § 1311(b)(2)(A) (emphasis added).

EPA of "the benefits derived from the application of its effluent reduction requirements. . . ."[100]

In the same vein, the general safety clause of the Food, Drug, and Cosmetic Act has, as discussed above, been given a pragmatic construction allowing for the evaluation of benefits—except where the categorical and absolute prohibition of the Delaney Clause applies. *See* p. 36 & n. 49, *supra*. A similar approach was taken in construing the pre-1972 provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which required EPA to deny (or withdraw) the registration of a pesticide if its use was "injurious to living man."[101] Although this statutory language did not expressly require consideration of benefits, the courts consistently recognized the obvious trade-offs involved and asked EPA to balance the benefits of restricting use of pesticides against the costs of doing so.[102]

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[100] Appalachian Power Co. v. Train, 545 F.2d 1351, 1361 (4th Cir. 1976). The fact that "some benefit" could be assumed to result from a reduction in the discharge of heat was held to be insufficient to satisfy the statutory provision. Rather, the court held that EPA must show what ecological benefits would result from the reduction in heat and compare the cost of achieving those benefits "with the benefits and costs associated with alternative levels of heat reduction." *Id.* 1364.

[101] 7 U.S.C. §§ 135(z)(2), (g) & (h), 135b (1970).

[102] *See, e.g.*, Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 594, 142 U.S. App. D.C. 74, 84 (1971) (holding that the decision to cancel the use of a pesticide "does not turn on a scientific assessment of hazard alone," and emphasizing that "[t]he statute leaves room to balance the benefits of a pesticide against its risk"); Environmental Defense Fund, Inc. v. EPA, 465 F.2d 528, 536, 150 U.S. App. D.C. 348, 356 (1972) (pre-1972 FIFRA provision required "a complex administrative calculus, in which the 'nature and magnitude of the foreseeable hazards associated with use of a particular

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In sum, the courts have construed other health and safety legislation in a pragmatic and relative manner, giving due regard to the overall objectives of the statutes and the practicalities of regulatory decision-making. In the absence of absolute statutory commands such as the Delaney Clause or the Endangered Species Act, the courts have rejected the tunnel-vision approach advocated by OSHA here, and instead have recognized that regulations should be based upon the best available information concerning what they will achieve and what they will cost.

II. THE COURT BELOW CORRECTLY SET ASIDE OSHA'S BENZENE STANDARD BECAUSE OSHA VIOLATED THE ACT'S STANDARD-SETTING REQUIREMENTS AND BECAUSE OSHA'S "APPRECIABLE BENEFITS" DETERMINATION WAS NOT SUPPORTED BY "SUBSTANTIAL EVIDENCE."

In light of the court's opinion and the preceding discussion of the Act's requirements (pp. 31-69), the reasons for affirmance of the decision below do not require lengthy elaboration. The court relied upon each of the provisions of the Act discussed above, and although its treatment was understandably not as exhaustive as the briefs before this Court, its basic holding is unassailable: OSHA must set standards that are reasonable and practical, and in order to do so, it must identify, at least roughly, the benefits that

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product' are weighed against the 'nature of the benefit conferred' by its use."); Stearns Elec. Paste Co. v. EPA, 461 F.2d 293, 307 (7th Cir. 1972) (Stevens, J.) (reaffirming the D.C. Circuit's interpretation of pre-1972 FIFRA provision as requiring a "delicate balance of [a pesticide's] benefits against its adverse effects").

each standard is expected to achieve and to consider those benefits in light of the costs imposed by the standard. Only if this is done can OSHA carry its "affirmative burden [of] demonstrat[ing] the reasonableness of [its] adopted standard."[103]

Without reaching the ultimate question of whether there is a "reasonable relationship" between the expected benefits and costs of OSHA's benzene standard (pp. 24-27 & nn. 44, 45, *supra*), the court below ruled that OSHA must make at least a "rough but educated estimate[ ] of the extent of benefits expected from reducing the permissible exposure limit from 10 ppm to 1 ppm." Pet. App. 21a (581 F.2d at 504). And that determination, like any determination under the Act, must be supported by "substantial evidence." *Id.* 18a (581 F.2d at 503). For where, as in this case, "the facts underlying the Secretary's determinations are susceptible of being found in the usual sense, that must be done, and the reviewing court will weigh them by the substantial evidence standard."[104]

[103] Atlantic & Gulf Stevedores, Inc. v. OSHRC, 534 F.2d 541, 551 (3d Cir. 1976). *Accord*, Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 487 F.2d at 351-53.

[104] Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 474. *See also* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975) (The substantial evidence standard applies whenever the agency's determination is "based in whole or in part on factual matters subject to evidentiary development."). In addition to this case, a number of other OSHA standards have been set aside for failure to satisfy the substantial evidence requirement. *See, e.g.*, Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 479-81; Florida Peach Growers Ass'n, Inc. v. Department of Labor, *supra*, 489 F.2d at 129-32; Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 487 F.2d at 351-54.

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The approach taken by OSHA in this case stands the Act on its head. Rather than looking first at what benefits, if any, a reduction of the permissible exposure limit would achieve, OSHA simply chose a number (1 ppm) and then set about showing that the affected industries could achieve that limit and still survive financially. After being confronted with uncontradicted evidence that its standard would achieve very little (if anything), OSHA felt compelled to mention the question of benefits in some fashion in its final Federal Register notice. But then, it did no more than proclaim summarily that its standard would produce "appreciable benefits"—without citing a shred of evidence in support of that determination. In short, OSHA's benzene standard is almost a textbook example of how not to regulate under the Act, and, accordingly, it was properly set aside by the court below.

A. The Court Below Correctly Held That OSHA Failed to Comply with the Standard-Setting Requirements of the Act.

The court below vacated OSHA's standard based on a combined reading of Sections 2(b), 3(8) and 6(b) of the Act. As interpreted by the court, these

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Indeed, even where OSHA shows that it is unable to make a factual determination because of the absence of evidence (a showing not made here), the courts have subjected the agency's explanation of its action to "exacting scrutiny" (Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 475) in order to ensure that OSHA has acted "in a manner reasonable under the state of the record before [it]." Florida Peach Growers Ass'n v. Department of Labor, *supra*, 489 F.2d at 129. *See also* Associated Indus. of New York State, Inc. v. Department of Labor, *supra*, 486 F.2d at 349-50; Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, *supra*, 503 F.2d at 1159-60. *Cf.* Appalachian Power Co. v. Train, *supra*, 545 F.2d at 1365.

provisions deprive OSHA of "the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost," and require OSHA to base its standards on "a number of pragmatic limitations" including "feasibil[ity]" and "specific kinds of information OSHA must consider in enacting standards." Pet. App. 15a-16a (581 F.2d at 502). Since we have already treated these provisions in detail, all that is required here is to summarize why the decision below was eminently sensible in light of these requirements and the record in this case.

Given OSHA's insistence that it may require the expenditure of whatever resources are necessary to reduce benzene exposures to 1 ppm (so long as the survival of the industries affected is not jeopardized), one might assume that benzene is the only workplace hazard with which the agency need be concerned. But, in fact, there are a multitude of potential occupational carcinogens that exhibit wide variations both in potency and in the conditions of workplace exposure.[105] What is more, these substances constitute only a fraction of the aggregate health and safety risks of varying severity present in the workplace and environment.

[105] As noted above (p. 4 n.5, *supra*), NIOSH has already identified approximately 2000 potential occupational carcinogens, many of which may ultimately be the subject of OSHA standards. These substances exhibit wide variations in carcinogenic potency. For example, aflatoxin, a powerful carcinogen present in consumer peanut products at tolerance levels set by FDA, is about 100,000 times more potent than benzene. A. 79-80; 39 Fed. Reg. 42748 (December 6, 1974). *See also* Add. C. 3c-4c & n. 7, *infra*.

Since the societal resources that can be devoted to these health and safety risks are not unlimited,[106] it is hardly surprising that the Act requires OSHA to identify, at least roughly, what its standards will accomplish.[107] That is, of course, what Congress intended when it required that standards be "feasible," and that they address "material" rather than inconsequential risks. For as Dr. Zeckhauser testified, the congressional objective of assuring the most adequate overall health and safety protection for employees can never be accomplished unless OSHA makes "a conscientious effort to determine what proposed policies will cost us, and what they will achieve for us." A. 136.

Examples of the kinds of "demonstrations" that would enable OSHA to make the "rough but educated estimate[]" of benefits required by the Act are the

[106] As noted in *Making Prevention Pay, the Final Report of the Interagency Task Force on Workplace Safety and Health*, p. VII-15 (1979):

> The cost of complying with OSHA is only part of the cumulative impact of Federal regulation on individual firms and their industries. There is growing concern that these cumulative impacts are costing jobs and draining substantial investment from new efforts at industrial innovation, while adding perhaps ¾ of 1% to the yearly rate of inflation. (Footnotes omitted.)

[107] As the Department of Health, Education and Welfare stressed in its departmental critique of OSHA's proposed standard; "real world pragmatism requires a systematic decision-making process" that takes account of the enormous variation in potencies and exposure patterns of cancer-causing agents. Letter of Charles Custard, Director of HEW Office of Environmental Affairs, dated July 12, 1977 (Exh. 205.A).

risk assessments prepared by Dr. Wilson and EPA. The usefulness of such "demonstrations" in standard-setting is proved by the "experience gained under this and other health and safety laws" —"experience" that OSHA is expressly directed to consider in formulating standards under Section 6(b)(5).

Specifically, as discussed in the record[108] and amplified in Addendum C, risk estimation techniques such as those employed by Dr. Wilson and EPA are used in decision-making by virtually every other federal health and safety agency, including the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Nuclear Regulatory Commission. These agencies have found, in the words of EPA, that the use of risk assessment techniques in regulating carcinogens represents "a significant step toward the objective of achieving real benefits in improved public health while avoiding the burden of undesirable regulatory action." 41 Fed. Reg. 21402, 21403 (May 25, 1976). *See* Add. C 8c-11c, *infra*.[109]

[108] *E.g.*, A. 42-45, 82, 159; API Post-Hearing Br. 92-93 (Exh. 217-33).

[109] If any further confirmation of the utility of these techniques were needed, it is found in the strong endorsements of groups as diverse as the National Academy of Sciences, the Interagency Regulatory Liaison Group (of which OSHA is a member), the President's Science Advisors and President's Council on Wage and Price Stability. Add. C 2c-7c, *infra*. Curiously, following the decision below, OSHA has not only publicly supported risk assessment techniques for evaluating the cost-effectiveness of its standards, but has gone so far as to employ such analyses in adopting and justifying standards for other toxic substances under Section 6(b)(5). *See* p. 57, *supra*; Add. C 11c-14c, *infra*.

In short, this "experience gained" under "other health and safety laws" imposes a heavy burden—which OSHA never undertook in its Federal Register notice—of explaining why it could not follow the example of other agencies that use "demonstrations" such as those provided by Dr. Wilson and EPA. On this record, therefore, the decision below should be affirmed even without reference to the other standard-setting requirements relied upon by the court. But when these other requirements, including the "reasonably necessary" provision of Section 3(8) and the "feasibility" and other "pragmatic limitations" of Section 6(b)(5), are taken into account, it becomes even more apparent that OSHA simply failed to adopt a standard that is based on "the best available evidence" concerning the reasonableness and practicality of reducing benzene exposures to 1 ppm.

B. The Court Below Correctly Held That OSHA's "Appreciable Benefits" Determination Was Not Supported by "Substantial Evidence" or Even a Rational Explanation.

As discussed above (pp. 17-21, *supra*), this is not a case where there was no evidence on the extent of benefits expected to result from OSHA's standard. Dr. Richard Wilson submitted a preliminary risk assessment for benzene based upon the very studies (particularly the Infante Study) cited by OSHA to establish an association between benzene exposure and an excess incidence of leukemia. Although Dr. Wilson employed a series of assumptions designed to

overstate the hazard,[110] his analysis indicated that the risk presented by benzene exposures of 10 ppm is exceedingly small, if it exists at all.

For example, Dr. Wilson estimated that the annual risk of cancer mortality faced by an employee exposed to benzene levels of 10 ppm is approximately the same as the additional cancer risk faced by a person who takes one round-trip transcontinental plane flight a month,[111] or who drinks slightly more than one cup of chlorinated tap water (or a beverage made from chlorinated tap water) each day.[112]

Three months later (and long before OSHA issued its final standard), Dr. Wilson's preliminary risk estimate was supported by the results of an entirely independent demonstration prepared by EPA. A. 14-29. Like Dr. Wilson's analysis, the EPA risk assessment was based largely on Dr. Infante's data

[110] For example, Dr. Wilson assumed that there is no threshold level for benzene-related leukemia, and he computed the risk of low level exposure on the basis of the most conservative linear extrapolation model. A. 164. In addition, Dr. Wilson doubled his risk estimate by assuming—without any real need to do so (*see* A. 33-34)—that one case of cancer will occur for each case of leukemia predicted by his model. A. 171.

[111] *See* A. 174. The plane-flight cancer risk is the result of exposure to cosmic radiation. Each one-way transcontinental flight presents an increased risk comparable to the additional hazard of an employee working at benzene levels of 10 ppm for two weeks.

[112] This risk results from the fact that chlorinated water may contain chloroform, a carcinogen. Each gallon of chlorinated drinking water that is consumed presents an increased risk comparable to the additional hazard to an employee who works at benzene levels of 10 ppm for two weeks. A. 174. A person drinking slightly more than one cup per day would consume two gallons within a two-week period.

and assumed a "linear non-threshold" dose-response relationship in order to obtain "an upper limit to the estimated risk." A. 15. Although OSHA produced the EPA report in an attempt to discredit Dr. Wilson's demonstration, an analysis of the EPA study showed that Dr. Wilson's estimate, if anything, overstated the maximum risk at 10 ppm and overestimated the maximum benefits of a reduction to 1 ppm. *See* p. 21, *supra*.[113]

But even if one insists that only Dr. Wilson's more conservative upper bound estimate should be used, *i.e.*, that the standard would prevent at most one case of leukemia and one other cancer every six years (see p. 20, *supra*), the benefits of the standard cannot reasonably be deemed to be "appreciable" without consideration of how the same resources might otherwise be allocated. For example, if the three billion dollar annual budget of the National Institutes of Health ("NIH")[114] were administered with the level of effectiveness represented by OSHA's benzene standard, NIH could expect to save little

[113] In light of this analysis, OSHA now attempts to discredit the EPA demonstration (which it submitted approvingly to the court below) by distorting its findings and asserting that the Infante data (on which EPA's analysis is based and on which OSHA relied in promulgating the standard) are "too imprecise to establish a dose-response relationship." OSHA Br. 70 n.56. In fact, while EPA acknowledged some margin for error, it stressed that the model it chose was "expected to give an *upper limit* to the estimated risk," and concluded that the actual risk "is not likely to be higher" than its estimate, "but it could be lower." A. 15, 16.

[114] THE BUDGET OF THE UNITED STATES GOVERNMENT—FISCAL YEAR 1980, 418 (1979).

more than ten lives per year.[115] Indeed, the evidence indicates that if all of society's resources were allocated with the cost-ineffectiveness of the benzene standard, the total gross national product would soon be exhausted without making even a minor dent in the vast array of health and safety problems confronting workers and others in our society. A. 175-76.

As discussed above (pp. 17-20, 71-75), the studies prepared by Dr. Wilson and EPA are examples of the type of evidence that should underlie an occupational health standard. Yet, OSHA presented no evidence demonstrating that Dr. Wilson's assessment (as supported by the results of the EPA demonstration) was inaccurate. Only in its final Federal Register notice did the agency deign to address the question of benefits at all, and then only to proclaim that the benefits are "likely to be appreciable." Nowhere did OSHA offer any evidence, or even a rational explanation, in support of this "appreciable" benefits "determination"—even though it is directly contradicted by the Wilson and EPA risk estimates.

In a series of legally irrelevant, *post-hoc* rationalizations,[116] OSHA's lawyers belatedly attempt to supply the explanation that the agency itself failed

[115] Dr. Wilson concluded, based on cost estimates developed by Arthur D. Little, that OSHA's standard would save two lives every six years at a cost of $300 million per life saved. A. 81. While this figure may be adjusted downward slightly in light of OSHA's final cost estimates (n.40, *supra*), NIH's $3 billion budget would be exhausted shortly after saving the tenth life if spent at the rate of the OSHA benzene standard.

[116] This Court has repeatedly emphasized that the *post-hoc* rationalization of counsel is entitled to no weight. *See, e.g.*, FPC v. Texaco Inc., 417 U.S. 380, 397 (1974); SEC v. Chenery Corp., 332 U.S. 194, 196 (1947).

to provide. But even when OSHA's own statements and the *post-hoc* rationalizations of its lawyers are viewed most charitably, they fail to justify the agency's action or to satisfy the "substantial evidence" requirement of Section 6(f) of the Act.

First, OSHA's lawyers claim that risk estimation techniques are too imprecise to be useful, citing (i) uncertainties in extrapolating from animal studies to humans, (ii) difficulties in determining the exposure levels involved in epidemiologic studies upon which extrapolations are based, and (iii) lack of assurance that an accurate dose-response extrapolation model has been selected. OSHA Br. 65-70. Even if these criticisms had any merit generally, they plainly do not apply here, where (i) interspecies extrapolation is unnecessary because the underlying evidence consists of human studies, (ii) the exposure levels in the relevant studies can be fixed within a reasonable range, and (iii) uncertainties about the dose-response function were resolved by utilizing the most conservative extrapolation models.[117]

Moreover, as attested by the witnesses below and the agencies that use risk estimation techniques, the inability to attain precision does not detract from the fact that even "rough but educated estimates" of the

[117] For this reason, the repeated references to the 5 million-fold variation in predicted risks from saccharin consumption (NRDC Br. 15, 23) have no relevance here. If anything, the fact that the most conservative extrapolation models may overstate human cancer risks supports the conclusion that the risk estimates of Dr. Wilson and EPA (which employed the most conservative assumptions) are probably greatly overstated.

degree of risk prevented can be of "immense value." A. 144. *See* pp. 20, 73-75, *supra*; Add. C 2c-11c, *infra*.[118]

Equally irrelevant is OSHA's argument that any estimate of health benefits must be rejected out-of-hand because OSHA is not permitted to value human life. OSHA Br. 62 n.52. In fact, no such valuation need be made. *See* p. 19, *supra*; Add. C 7c, *infra*. Nevertheless, identification and assessment of the degree of risk prevented (*i.e.*, the benefits) is essential if the most adequate overall protection is to be provided, since, in words of the President's Council, "OSHA is faced with a finite quantity of society's resources or maximum costs that can be allocated to worker safety and health in any industry." A. 126.

Finally, OSHA's rejection of Dr. Wilson's risk assessment for benzene on the ground that it was inconsistent with the results of the Infante Study (Pet. App. 161a-162a) simply makes no sense. In fact, as discussed above, Dr. Wilson's estimate was largely based on Dr. Infante's findings, as was the subsequent, confirmatory demonstration provided by EPA.[119]

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[118] As OSHA implicitly acknowledges, once an appropriate extrapolation model is selected, all of the relevant data points along the line between high level exposure and very low level exposure can be determined. OSHA Br. 64 n.53. Consequently, contrary to OSHA's implication (*id.* 64), a requirement that OSHA assess the benefits that would be expected from appropriate segmental reductions in permissible exposure levels would not create any additional burden for the agency.

[119] In support of its outright rejection of Dr. Wilson's demonstration, OSHA's Federal Register notice observes only that the Infante Study "disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period." Pet. App. 161a. What OSHA fails to disclose (if, indeed, it ever considered comparing Infante's and Wilson's results) is that Infante's findings are equivalent to slightly *less* than 2 cases every six years. Dr. Wilson reached approximately the same result in applying the Infante data to a worker population which, while larger (30,000), is exposed to far lower benzene levels (considerably less than 10 ppm on the average, instead of 100 ppm as in the Infante Study).

(footnote continued on next page)

In sum, neither OSHA nor its lawyers have managed to articulate any rational explanation for rejecting the best available evidence regarding benefits in the present case, or for OSHA's failure to make any attempt to estimate the benefits of the standard on its own. The fact is that OSHA simply chose to "bury[ ] its head in the sand."[120] It identified no evidence supporting its summary "determination" that the benefits of its standard are "likely to be appreciable" (Pet. App. 162a), and was unable to explain how such a conclusion could be squared with the evidence pointing in the opposite direction.[121] Far from being supported by substantial evidence, OSHA's "appreciable benefits" determination rests upon nothing more than a "conclusory statement

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(footnote continued from previous page)

OSHA's lawyers provide other *post-hoc* rationalizations for rejecting Dr. Wilson's estimates (OSHA Br. 69 n.56) which also lack foundation. Thus, rather than underestimating the number of workers exposed to benzene levels below 10 ppm, as OSHA claims, Dr. Wilson based his estimate upon the number of such workers provided by OSHA's own contractor, A.D. Little—an estimate that OSHA never disputed and which its lawyers cite with approval (*id.* 24 n.26). And, far from giving "no basis for his conclusions at the hearing" (*id.* 69 n.56), Dr. Wilson carefully detailed the basis and rationale for his estimate in his direct testimony and during three hours of cross-examination by OSHA, and union representatives. Tr. 2717-2827.

[120] Testimony of Dr. Richard Zeckhauser, A. 47. Dr. Roy Albert, the Head of EPA's Carcinogen Assessment Group (*See* Add.C 8c-9c, *infra*) has agreed with Dr. Zechauser that OSHA's approach of ignoring risk assessment is "like the ostrich putting its head in the sand." Carter, *Dispute Over Cancer Risk Quantification*, 203 SCIENCE 1324, 1325 (March 30, 1979).

[121] All it could offer was a policy assumption that "exposure to lower levels is accompanied by a reduced risk . . . ." Pet. App. 160a. However, the record evidence indicated that the leukemia risk at an exposure level of 10 ppm was already minuscule and that a reduction of exposures to 1 ppm would yield only the most insignificant additional protection. Consequently, the assumption that lower exposures are accompanied by lower risks provides no justification whatsoever for a determination of "appreciable benefits" in the circumstances of this case.

of reasons,"[122] unsupported by a "scintilla" of evidence,[123] or even by a rationally articulated explanation of the course of action the agency chose to follow.[124]

To sustain OSHA's action on such a record, a reviewing court would have to sanction the development of occupational health and safety standards upon precisely the sort of unsubstantiated "views and arguments" that the substantial evidence requirement was intended to preclude. Consequently,

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[122] Dry Color Mfrs. Ass'n v. Department of Labor, *supra*, 486 F.2d at 106.

[123] *Cf.* Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). *See also* Consolo v. FMC, 383 U.S. 607, 619-20 (1966); May Trucking Co. v. United States, 593 F.2d 1349, 1352 (D.C. Cir. 1979).

[124] The importance of careful and rational articulation, even of policy determinations, has been emphasized repeatedly by this Court. *See, e.g.*, Baltimore & Ohio R.R. v. Aberdeen & Rockfish R.R., 393 U.S. 87, 91-92 (1968); NLRB v. Metropolitan Life Ins. Co., 380 U.S. 438, 442-43 (1965); Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167-68 (1962); SEC v. Chenery Corp., 332 U.S. 194, 196-97 (1947). It has also been stressed by courts reviewing OSHA standards. *See, e.g.*, Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 475-76; Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, *supra*, 503 F.2d at 1159-60.

The articulation requirement established by basic principles of administrative law is underscored by statute and regulation on OSHA's case. Thus, Section 6(b)(8) of the Act requires that where, as here, OSHA adopts a standard which "differs substantially from an existing national consensus standard," OSHA's statement of reasons—required by Section 6(e), 29 U.S.C. § 655(e)—must explain "why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard." 29 U.S.C. § 655(b)(8). OSHA's own procedural regulations amplify these requirements by providing that the statement of reasons must "show the significant issues which have been faced and . . . articulate the rationale for their solution." 29 C.F.R. § 1911.18(b).

OSHA's "appreciable benefits" determination, and the standard that rests upon that determination, were properly set aside by the court below.

CONCLUSION

The judgment of the court below should be affirmed.

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ADDENDUM A

STATUTORY PROVISIONS INVOLVED

Section 2(b) and paragraphs (3), (5), (6) and (7) thereof (29 U.S.C. § 651(b)(3), (5), (6) & (7)) provide as follows:

> The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—
>
> * * *
>
> (3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce . . . ;
>
> * * *
>
> (5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;

* * * *

Section 3(8) of the Act (29 U.S.C. § 652(8)) provides:

(8) The term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6(b)(1) of the Act (29 U.S.C. § 655(b)(1)) provides:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers

or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act.

Section 6(b)(5) of the Act (29 U.S.C. § 655(b)(5)) provides:

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and

experience gained under this and other health and safety laws.

Section 6(b)(8) of the Act (29 U.S.C. § 655(b)(8)) provides:

> (8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

Section 6(e) of the Act (29 U.S.C. § 655(e)) provides:

> (e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this Act, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

Section 6(f) of the Act (29 U.S.C. § 655(f)) provides:

> (f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person

> resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

ADDENDUM B

LEGISLATIVE HISTORY OF THE STANDARD-SETTING PROVISIONS OF THE OCCUPATIONAL SAFETY AND HEALTH ACT

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ADDENDUM B

LEGISLATIVE HISTORY OF THE STANDARD-SETTING PROVISIONS OF THE OCCUPATIONAL SAFETY AND HEALTH ACT

INTRODUCTION

The Occupational Safety and Health Act was passed in late 1970 after what was characterized as "the most bitter labor-management fight in years." Leg. Hist. 193. The debate in Congress focused, not on the need for legislation providing for occupational safety and health standards, but rather on who (or what body) would promulgate them, and under what criteria they would be developed and reviewed by the courts.

"The shared objective" of the two opposing camps was "to reduce the number and severity of work-related injuries and illnesses which, in spite of current efforts, continue at high levels, and . . . cause human misfortune and economic waste." Leg. Hist. 297 (remarks of Rep. Steiger).

Although both safety and health hazards figured significantly in the congressional debate, occupational health was of particular concern. Congress recognized that the number of toxic chemicals and harmful physical agents in the workplace is increasing,[1] and that the resulting health hazards pose regulatory problems "often different from those involved in occupational safety," since they necessitate "exploring ways to discover latent diseases, establishing causal connections between diseases and work in

[1] *See* Leg. Hist. 142 (Senate Report); Leg. Hist. 845-46 (House Report).

environmental conditions, and conducting research relating to health problems."[2]

In spite of the general agreement that legislation was needed, and that the more subtle problems of occupational health should be considered, Congress was sharply and nearly evenly divided over the means to achieve its "shared objective." The congressional debate focused on three key issues:

(1) who (or what body) would promulgate standards and adjudicate violations;

(2) what criteria and considerations would govern standard-setting; and

(3) what evidentiary record would be required and what test for judicial review would apply.

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[2] S. 2788 § 2(b)(5), Leg. Hist. 33; S. 4404 § 2(b)(6), Leg. Hist. 75; H.R. 13373 § 2(b)(5), Leg. Hist. 681; H.R. 16785 § 2(b)(4), Leg. Hist. 723; H.R. 19200 § 2(b)(6), Leg. Hist. 765.

Thus, *every* occupational safety and health bill contained in the Senate Committee Print of the legislative history of the Act included among its purposes to provide for research in the field of occupational safety and health, and directed the Department of Health, Education and Welfare to conduct research, and specifically authorized the Secretary of Labor to contract for research or other studies. S. 2193 (as introduced) §§ 2(b)(3), 15, Leg. Hist. 2, 23-24; S. 2788 §§ 2(b)(4), 17, Leg. Hist. 33, 63-65; S. 4404 §§ 2(b)(5), 23, Leg. Hist. 75, 126-28; S. 2193 (as reported) §§ 2(b)(2), 18, 19, Leg. Hist. 234, 274-82; S. 2193 (as passed by Senate) §§ 2(b)(2), 19, 20, Leg. Hist. 530, 574-82; H.R. 843 §§ 2(b)(3), 15, Leg. Hist. 600, 621-23; H.R. 3809 §§ 2(b)(3), 15, Leg. Hist. 630, 651-52; H.R. 4294 §§ 2(b)(3), 15, Leg. Hist. 661, 672-75; H.R. 13373 §§ 2(b)(4), 17, Leg. Hist. 681, 711-13; H.R. 16785 (as introduced) §§ 2(b)(3), 19, Leg. Hist. 722-23, 753-57; H.R. 19200 §§ 2(b)(5), 23, Leg. Hist. 765, 816-18; H.R. 16785 (as reported) §§ 2(b)(3), 19, Leg. Hist. 832, 841-842; H.R. 16785 (as passed by House) §§ 2(b)(5), 23, Leg. Hist. 1092, 1107-08.

One faction in both houses supported the Daniels bill (H.R. 16785) and a closely similar bill (S. 2193) sponsored by Senator Williams. These bills provided for standard-setting by the Secretary of Labor under informal rulemaking procedures with judicial review based on the "arbitrary and capricious" test. They also vested in the Secretary of Labor the responsibilities of investigating, prosecuting, and adjudicating violations of standards.[3]

The Daniels and Williams bills provoked vigorous opposition in both houses and by the Administration. Opponents charged that these proposals created "a great potential for abuse" and might result in "frivolous disruptions of industrial production under arbitrary and arrogant administration by the U.S. Department of Labor." Leg. Hist. 420, 1080. These concerns arose both because the Daniels and Williams bills prescribed "unfair regulatory procedures" which "permit adoption of administrative regulations based on 'views and arguments' rather than solely on probative evidence," and because they would permit employer interests to be largely ignored by the Secretary of Labor, "who has traditionally been the voice of labor in the administration." Leg. Hist. 474-75, 884, 982, 1014.

Opponents of the Daniels and Williams bills supported far different proposals—initially an Administration bill (S. 2788, H.R. 13373) sponsored by Senator Javits, and later the Administration-backed Steiger-Sikes Substitute (H.R. 19200, S. 4404). The latter bill: (i) placed standard-setting authority in

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[3] *See* H.R. 16785 (as introduced) §§ 7(a)(2), 9-11, Leg. Hist. 729-30, 735-42; S. 2193 (as introduced) §§ 6, 8-10, Leg. Hist. 240-46, 249-61.

an independent board; (ii) provided formal rulemaking procedures with judicial review based on the "substantial evidence" test; and (iii) effected a "separation of powers" by creating an independent body to adjudicate enforcement cases.[4]

What ultimately emerged was a compromise between the Daniels-Williams proposals and the Administration approach. In return for leaving standard-setting authority in the Labor Department, Administration forces obtained: (i) substantive and evidentiary limitations on the Secretary's standard-setting authority; (ii) inclusion of the "substantial evidence" review standard; and (iii) an independent board (the Occupational Safety and Health Review Commission) to adjudicate enforcement cases. This Addendum treats the legislative history of these developments in chronological order.

A. Consideration by the House Committee on Education and Labor

The first major confrontation between the two opposing camps took place in the House Committee on Education and Labor. By a narrow margin (19-15), the House Committee voted down the Administration-backed Steiger-Sikes Substitute (H.R. 19200), which had been offered in committee by Representatives Steiger (R.-Wisc.) and Hathaway (D.-Me.) as a "bipartisan compromise" between the initial Administration bill (H.R. 13373) and the Daniels bill (H.R. 16785). Leg. Hist. 988, 1057. Instead, the Committee favorably reported the Daniels bill with amendments which, with one exception, made

[4] *See* H.R. 19200 §§ 6, 8-11, Leg. Hist. 770-76, 779-96.

no significant change in the major provisions of the bill as introduced.[5]

The exception was the addition of a provision recognizing the somewhat different problems presented by occupational health hazards. The House Report observed that, unlike safety hazards, which "are often immediately apparent" and where it is usually possible to identify "a clear cause and effect" relationship, "[d]iseases resulting from occupational health hazards may not become known until years after continuous exposure have elapsed." This detection problem arises because of the "long latent period[s]" between exposure to a hazard and the onset of disease, or because chronic exposure may be required before health effects appear. Leg. Hist. 853-54.

For these reasons, the Committee elaborated the following special standard-setting criteria, which were to apply specifically to "occupational health standards" (Leg. Hist. 848):

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health, or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[6]

[5] *See* H.R. 16785 (as reported) §§ 7, 9-11, Leg. Hist. 934, 940-43, 949-55.

[6] H.R. 16785 (as reported) § 7(a)(4), Leg. Hist. 943.

Although this provision was considered necessary to account for the different problems presented by occupational health hazards,[7] the Committee did not indicate that it wanted stricter standards for health (as opposed to safety) hazards. To the contrary, the Committee stressed that it did not intend to provide absolute health protection. Thus, the Committee made clear that "while [health standards] will reflect" NIOSH criteria "describing medically acceptable tolerance levels of exposure to harmful substances or conditions over a period of time, . . . they may be modified by practical considerations such as feasibility, means of implementation, and the like." Leg. Hist. 857-58.

With this addition, the Daniels bill was reported by the House Committee, but not without vigorous dissents from supporters of the Administration approach, who complained bitterly about the majority's refusal to entertain even the slightest compromise. The minority considered the Daniels bill "unacceptable" because it "ignore[d] the element of fairness to those required to comply with the Act." Leg. Hist. 877. Citing the "substantial financial impact" the Act would have on employers, they denounced the bill for allowing standards to be based on " 'views and arguments' rather than probative

[7] As explained by the House Committee, this provision would require the Secretary, in formulating "occupational health standards," to act "on the basis of the best available evidence," so as not to "be paralyzed by debate surrounding diverse medical opinions." Leg. Hist. 848.

evidence." Leg. Hist. 884.[8] By contrast, they stressed the need for standards to be established by an independent board "based on substantial evidence" and accordingly promised to offer the Steiger-Sikes bill as a substitute for the Daniels bill on the House floor. Leg. Hist. 881-82.

Before the full House could consider the Committee bill, however, the Senate Labor and Public Welfare Committee began its own review of a closely-similar bill introduced by Senator Williams. It is to this Senate Committee consideration that we now turn.

B. Consideration by the Senate Committee on Labor and Public Welfare

Like its House counterpart, the Senate Labor and Public Welfare Committee voted to reject the Administration-backed Steiger-Sikes Substitute (S. 4404 in the Senate), and to report favorably an amended version of the bill previously introduced by Senator Williams (S. 2193, Leg. Hist. 1). The Senate Committee's bill was similar in most major respects to the Daniels bill reported in the House,[9] and was criticized by the minority for much the same reasons as had been advanced in the House. Leg. Hist. 200-03. Although the Senate Committee had for the most part developed its bill independently, it specifically chose to follow the House Committee's approach of providing special criteria for setting health standards. Leg. Hist. 242.

[8] The minority charged that there was "[n]o reason" for "this deviation from regular and fair procedures," and that under the Committee bill, "[t]he requirements that administrative decisions be based on facts and sound reasons mean little." Leg. Hist. 884.

[9] *See* S. 2193 (as reported) §§ 6, 8-10, Leg. Hist. 240-46, 249-61.

But unlike their House counterparts, the Senate Committee's minority members were able to secure a series of compromises relaxing several of the more objectionable features of the Williams bill. *See* Leg. Hist. 196-98. Two of these amendments, which affected the standard-setting criteria incorporated from the House Committee's bill, were designed to assure that standards would be "reasonable" and "practical," and that the Secretary would, in every case, base his standards on all available scientific evidence.

1. The Javits "feasibility" amendment

The first minority amendment was suggested by Senator Javits, the ranking minority member of the Senate Committee, and sponsor of the initial Administration bill (S. 2788). To allay the concerns of those, including Senator Javits, who feared that the Daniels bill "might be interpreted to require absolute health and safety protection in all cases, regardless of feasibility" (Leg. Hist. 197), the Senate Committee amended the Daniels criteria—to read "the standard which most adequately *and feasibly* assures, . . ."[10]—thereby signifying the Committee's intent that "standards promulgated under section 6(b) shall represent feasible requirements." Leg. Hist. 147.

By persuading the Committee to adopt his "feasibility" amendment (*see* Leg. Hist. 418), Senator Javits succeeded in reconciling the Williams bill with the Administration view on this issue. The Administration's initial proposal, authored by Senator Javits himself (Leg. Hist. 316), had expressly contemplated that all health and safety standards be

[10] S. 2193 (as reported) § 6(b)(5), Leg. Hist. 242 (emphasis added).

"feasible," meaning not only that standards be "technologically feasible" but also "reasonable" and "practical" as well.

Specifically, Senator Javits' bill (S. 2788) would have required a National Occupational Safety and Health Board to submit any proposals for permanent standards "to the appropriate national standards-producing organization" for a report on "the *technical feasibility, reasonableness* and *practicality* of such standard."[11] Senator Javits described this as "a report on the feasibility of the proposed standards."[12] This "feasibility report" was to be considered by the Board (along with other record evidence) in formulating its standards. Moreover, the Secretary of Labor or the Secretary of Health, Education and Welfare was permitted to force a reconsideration by filing a "written objection" that the standard chosen "is not feasible."[13]

Accordingly, although the Senate Committee refused to adopt the Administration proposal for standard-setting by an independent board, it nevertheless accepted Senator Javits' compromise requiring that standards set by the Secretary of Labor be "feasible" in the sense of being reasonable and practical. This was the meaning of "feasible" as understood, not only by Senator Javits, but by other members of the Senate Committee as well. *See* p. 17b, *infra*.

[11] S. 2788 § 4(c), Leg. Hist. 38-39 (emphasis added).
[12] 115 Cong. Rec. 22517 (August 6, 1969).
[13] S. 2788 § 4(c)(2), (3), Leg. Hist. 39-40.

2. The requirement that standards be based on "the best" and "latest available" scientific evidence, "research, demonstrations, [and] experiments," plus "experience gained under this and other health and safety laws"

Apart from the "feasibility" amendment, the Senate Committee engrafted a series of additional requirements onto the Daniels standard-setting criteria. As redrafted by the Senate Committee, Section 6(b)(5) read as follows:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available [professional] evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. *Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.*[14]

These additional provisions were designed to require the Secretary to act, not on the basis of "views" or "arguments" (as permitted under the

[14] S. 2193 (as reported) § 6(b)(5), Leg. Hist. 242 (new material in italics, deleted material in brackets).

House Committee's criteria, *see* p. 6b-7b, *supra*), but rather on "the best available" scientific and factual evidence. By providing that standards "shall be based on" scientific data—*i.e.*, "research, demonstrations, experiments, and . . . other information"—the Committee underscored its intent that the Secretary develop scientifically-based, factually supportable standards.[15]

Moreover, the Senate Committee's amendments prohibited the Secretary from ignoring advances in the state of the art for regulating health or safety hazards, and required instead that he consider "the latest available" scientific knowledge "in the field," particularly where reflected in "experience under this and other health and safety laws."

C. Consideration by the Full Senate

Notwithstanding their success in committee, Senate supporters of the Administration view, led by Senator Dominick, continued to urge passage of the Steiger-Sikes Substitute during the Senate debates.

[15] The obligation imposed on the Secretary to act on the basis of "research, demonstrations, [and] experiments" was complemented by the "research" provisions already in the Committee bill. Section 19 of the bill created a new National Institute of Occupational Safety and Health ("NIOSH") to conduct research and experimental programs. Leg. Hist. 279-82. Section 18(b) of the bill specifically authorized the Secretary to enter into contracts with public or private organizations "for the purpose of conducting studies related to the establishing and applying of occupational safety and health standards. Leg. Hist. 277. Apparently recognizing that research activities contracted for by the Secretary would often be different from and supplementary to those of NIOSH, Section 18(b) directed the Secretary to cooperate with the Department of Health, Education and Welfare (of which NIOSH is a part) "to avoid any duplication" of research efforts. *Id.*

As summarized below, their efforts resulted in further limitations on the Secretary's power, including: (i) a split of authority between the Secretary of Labor and an independent Review Commission; and (ii) additional modifications in the standard-setting criteria of Section 6(b)(5).

1. Split of authority between the Secretary of Labor and an independent Review Commission.

During the Senate floor debates, supporters of the Administration approach continued to express concern about the "unfair regulatory procedures" (Leg. Hist. 298) of the Committee bill, and urged the Senate to pass "a balanced bill," because "[w]e cannot just have a bill set up for the employee and not worry about the employer, because someone has to provide the job." Leg. Hist. 320. One of the "unfair regulatory procedures" they cited was an undesirable concentration of power in the Secretary of Labor. Leg. Hist. 298. Senate supporters of the Administration approach also charged (i) that the informal rulemaking procedures of the reported bill were inadequate because they did not involve the making of a "formal record," so that, as a result, "standards could not be based on substantial evidence of record" (Leg. Hist. 298-99); and (ii) that the "arbitrary and capricious" standard of review prescribed in the Committee bill seriously undermined the right to a judicial remedy because "it will be very, very strange if they can ever win a case." Leg. Hist. 343-44.

The Senate ultimately adopted a compromise between the Committee bill and the Steiger-Sikes

Substitute. Although a motion to table the Steiger-Sikes measure was passed by a narrow margin (41 to 39), the Senate approved another pending amendment—a compromise sponsored by Senator Javits—which incorporated into the Committee bill the Steiger-Sikes provision for an independent body to adjudicate enforcement cases. Leg. Hist. 445, 478.[16] By achieving a "separation of powers" in the overall administration of the Act, this amendment eliminated one of the major reasons for concern about the issuance of arbitrary regulations under the Williams Bill.[17]

2. Further amendments to the standard-setting provisions on the Senate floor

Not satisfied with the Senate Committee amendments to the standard-setting provisions (*see* pp. 7b-11b, *supra*), proponents of the Steiger-Sikes bill continued to press for further amendments to the Committee bill on the Senate floor. Among the most significant of these floor amendments was a clarification of the first sentence of Section 6(b)(5).

During the floor debates, Senators Dominick and Saxbe, among others, expressed reservations that Section 6(b)(5)—even after the compromise "feasibility" amendment and inclusion of a require-

[16] Senator Javits' compromise amendment had previously failed in committee by a vote of 10 to 7. Leg. Hist. 194-95.

[17] However important this compromise may have been, other concerns remained unsatisfied (*see* p.12b, *supra*) and as a result the Steiger-Sikes proponents later succeeded in persuading the House to pass their Substitute. *See* p. 18b, *infra*. Consequently, the House-Senate Conference Committee was faced with the need to make still further compromises. *See* pp. 19b-21b, *infra*.

ment that standards be based on scientific evidence—was still "inherently confusing and unrealistic." Leg. Hist. 367.

First, the apparent prohibition against "any" impairment of health and "any" dimunition of life expectancy was said to be impractical since some risk was thought to be the handmaiden of all employment. Leg. Hist. 337. Senate Saxbe stressed the inherent trade-off between employment and health since "any type of exposure is going to affect" functional capacity and life expectancy. Leg. Hist. 338. He illustrated this point as follows:

> One example is working in a paint shop or working in an automobile line, a final assembly line, or on a paint line .... [S]ubstantial skill is required to be an automobile painter, which means that the person who acquires this skill already has a substantial buildup of inhaled paint particles before he achieves the skill required to hold a steady job.

Leg. Hist. 338.

Citing similar examples of a bus or street car driver constantly exposed to risks of air pollution and traffic accidents (Leg. Hist. 423, 481), Senator Dominick sought to avoid any implication that standards "must assure that there will not be any risk at all." Leg. Hist. at 481. For "there is no way a criteria [sic] can be established so that an employee would not be faced with some risks for the period of his working life." Leg. Hist. 481-82.

A closely-related concern was that the purpose of Senator Javits' "feasibility" amendment had not

been given full effect in the Committee's bill. As Senator Dominick explained, the first sentence of Section 6(b)(5)

> could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or [diminished] life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which most "adequately" and "feasibly" assures the elimination of the danger would be the prohibition of the occupation itself.

Leg. Hist. 367 (emphasis in original). *See also* Leg. Hist. 480-81.

In Senator Dominick's view, although it was appropriate to recognize that health hazards may pose new and different problems because of long latency periods or the effects of cumulative exposures, the degree of protection provided to workers should be determined based on the same overriding regulatory considerations applicable to safety hazards. In either case, the fundamental question is how much protection to provide (or how much risk to eliminate), for, as Senator Dominick stressed, "[i]t is unrealistic to attempt, as this section apparently does, to establish a utopia free from hazards. Absolute safety is an impossibility . . . ." Leg. Hist. 480.

Consequently, Senator Dominick concluded that it would be better to drop the first sentence of Section 6(b)(5) altogether and assume that the Secretary

would take the special problems of latency periods and cumulative exposures into account in regulating health hazards. Leg. Hist. 480. But after offering an amendment to that effect, Senator Dominick moved that it "be temporarily laid aside" in light of "modifications" that he was discussing with Senators Williams and Javits. Leg. Hist. 482.

Senator Dominick then introduced a "substitute amendment" which he had "worked . . . out" with Senators Williams and Javits and which he believed was "agreeable to all." Leg. Hist. 502. This substitute amendment revised the first sentence of Section 6(b)(5) as follows:

> The Secretary, in promulgating standards *dealing with toxic materials or harmful physical agents* under this subsection, shall set the standard which most adequately [and feasibly] assures, *to the extent feasible*, on the basis of the best available evidence, that no employee will suffer *material* [any] impairment of health or functional capacity [or diminished life expectancy] even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

Leg. Hist. 502 (new material in italics, deleted material in brackets).

This consensus amendment, which was adopted without objection, accomplished three things.

First, it clarified that the first sentence of Section 6(b)(5) was addressed to "toxic materials or harmful physical agents," thereby making explicit

what the House Committee had originally intended when it first drafted the provision—*i.e.*, that it applied only to "occupational health standards." *See* pp. 5b-6b, *supra*.[18]

Second, the amendment developed by Senators Dominick, Williams and Javits gave full effect to the intent of Senator Javits' "feasibility" amendment by rewording the provision to make feasibility a clear limitation. As explained by Senator Dominick:

> What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected.

Leg. Hist. 502. The committee chairman, Senator Yarborough, explained that with this amendment, "[a]ll the bill requires is reasonable safety devices" and "reasonable safety standards." Leg. Hist. 511, 512.

Third, Senator Dominick's consensus amendment substituted the word "material" for the word "any." This change further underscored Senator Javits'

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[18] Senator Dominick's amendment also left no doubt that the second and third sentences of Section 6(b)(5) apply to *all* permanent standards, including safety standards. Specifically, the introductory phrase of the second sentence was changed (*see* p. 10b, *supra*, for previous text) to refer to "*standards under this subsection*" —*i.e.*, subsection (b) of Section 6, providing for the development of both health standards *and safety* standards. Leg. Hist. 502.

feasibility amendment by limiting the Secretary's standard-setting power to "material impairment" of health. From the legislative debate summarized above, it is apparent that this change addressed the concerns expressed by Senators Dominick and Saxbe that the expression "any impairment" would have allowed the Secretary to regulate immaterial or inconsequential "risks." *See* pp. 14b-15b, *supra*.

After this and other amendments not directly relevant here, the Senate passed the Committee bill on November 17, 1970. Leg. Hist. 528.

D. House Rejection of the Daniels Bill and Passage of the Steiger-Sikes Substitute

Despite these Senate amendments, supporters of the Administration view in the House continued to press for passage of the Steiger-Sikes Substitute when the full House took up the Daniels bill on November 23, 1970. Support for the Administration view proved even stronger in the House than in the Senate—so strong, in fact, that it soon became clear that the real choice in the House was between the Steiger-Sikes Substitute and no legislation at all. Leg. Hist. 1089.[19] When the issue came to a vote on November 24, 1970, the Steiger-Sikes Substitute prevailed 220 to 172. Leg. Hist. 1112.

[19] The vigorous opposition to the Daniels bill (as reported by the House Committee) was based on objections previously discussed at pp. 3b, 6b-7b, 12b *supra*. *E.g.*, Leg. Hist. 1013, 1014 (Rep. Scherle), 1016 (Rep. Erlenborn), 1053, 1062 (Rep. Sikes).

E. Further Compromises in the House-Senate Conference Committee.

House passage of the Steiger-Sikes Substitute set the stage for still further compromises. To be sure, both houses, as a result of Senator Javits' amendment on the Senate floor, had passed the Steiger-Sikes proposal for an independent Review Commission to adjudicate enforcement cases. Moreover, House proponents of the Steiger-Sikes Substitute were apparently satisfied with the standard-setting requirements in Section 6(b)(5) of the Senate bill, including the evidentiary requirements of the second and third sentences, Senator Javits' "feasibility" amendment, and Senator Dominick's clarification of the first sentence of Section 6(b)(5).[20] Nevertheless,

[20] The House bill contained no standard-setting criteria for "toxic materials or harmful physical agents" corresponding to the first sentence of Section 6(b)(5) of the Senate bill, but instead directed that standards "carry out the purposes of this Act." Leg. Hist. 1121. In effect, the House had adopted Senator Dominick's initial approach of assuming, without specific statutory direction, that the standard-setter would take the special regulatory issues posed by health hazards into account in developing standards which meet the overall goals of the Act. *See* pp. 15b-16b, *supra*. Since Senator Dominick's substitute amendment accomplished the same purpose, there was no serious difference between the House and Senate provisions.

Nonetheless, the House Conferees won approval for a provision allowing individual employers to obtain temporary variances from standards because of their inability to obtain the personnel, materials or equipment needed for compliance. Leg. Hist. 1188.

two key issues remained: (i) who (or what body) would formulate occupational safety and health standards; and (ii) what would be the test for judicial review of such standards.

Because both houses had acted so late in the legislative session (November 17 in the Senate and November 24 in the House), the Conference Committee had little time to resolve these remaining differences before adjournment. Whether because of the impending adjournment or for other reasons, the Committee quickly reached an acceptable compromise. The anti-Administration forces prevailed on who (the Secretary of Labor) would be authorized to set occupational health and safety standards, and Administration forces prevailed on whether the stricter test ("substantial evidence") would govern judicial review under the Act.[21]

[21] There were, of course, other points on which a compromise was reached. For example, the Conference Committee adopted the House bill's statement of the Act's purposes, which was "more detailed" (Leg. Hist. 1185), and which emphasized more strongly the role of research in proper implementation of the Act. These House provisions (now Sections 2(b)(5) & (6) of the Act) provide expressly that the Act's overall purpose of "safe and healthful workplaces so far as possible" shall be achieved, *inter alia*, "by providing for research in the field of occupational safety and health" and "by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions and conducting other research relating to health problems." Leg. Hist. 1155. The Committee also adopted the broader House provision (Section 20(c)) authorizing the Secretary to contract for studies relating to all of his responsibilities under the Act, rather than only with respect to his standard-setting responsibilities. *See* Leg. Hist. 1176.

It was the Senate's acquiescence in the more rigorous "substantial evidence" test (Section 6(f)) that led proponents of the Steiger-Sikes Substitute to recommend passage of the Conference bill. Thus, Congressman Steiger, the floor leader for the Steiger-Sikes Substitute, urged his colleagues to approve the Conference Report, but only because the "substantial evidence" test would provide adequate protection against fears that employer interests might be ignored by the Secretary:

> The Secretary's standard will only be sustained by the court if it is supported by "substantial evidence on the record considered as a whole." Thus, the Secretary must have a record on which to base his findings and to serve as the basis for judicial review. The act does not provide for an independent board for standard-setting as did the House bill. However, court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that the conference report should be adopted.

Leg. Hist. 1218.

After Senate approval on December 16, the Conference Report, with Representative Steiger's support, passed the House by a vote of 308 to 60 on December 17, 1970. Leg. Hist. 1225. Twelve days later, on December 29, 1970, the Conference Bill became law. Leg. Hist. 1229.

ADDENDUM C

DECISIONS INVOLVING HEALTH RISKS: THE EXPERIENCE OF OSHA AND OTHER HEALTH AND SAFETY AGENCIES

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ADDENDUM C

DECISIONS INVOLVING HEALTH RISKS: THE EXPERIENCE OF OSHA AND OTHER HEALTH AND SAFETY AGENCIES

In an effort to undercut the decision below, counsel for OSHA and others supporting reversal attempt to leave the erroneous impression that techniques for evaluating health risks are too imprecise to be helpful, and that they are of no use in deciding how health protection resources should be allocated. OSHA Br. 65-70. Likewise, OSHA wrongly implies that it would face regulatory paralysis or inordinate delays if it considered or used such techniques in decision-making.

But, as we show in this Addendum,[1] qualitative and quantitative techniques for assessing health risks and for estimating the likely benefits of regulation have been common since the 1960's (*see* nn. 25 & 26 *infra*).[2] Indeed, virtually every other federal

[1] In contrast to the briefs supporting reversal, which rely heavily on selective citations from the general literature, this Addendum will rely on the record in this case, and the actions of OSHA and other federal agencies taken after full, public rulemaking proceedings. Respondents also draw from the rulemaking record on OSHA's Proposed Rule for the *Identification, Classification, and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54148 (October 4, 1977). References to testimony in that proceeding will be identified as part of the "OSHA Cancer Policy Record," and are available for inspection at OSHA's Technical Data Center in Docket H-90.

[2] Indeed, even techniques for comparing costs and benefits —although not an issue in this case—have long been used by federal agencies. For example, the Army Corps of Engineers has used such cost-benefit analyses for decades in carrying out its mandate under the Flood Control Act of 1936.

health and safety agency uses such techniques, and even OSHA has employed them on occasion. Moreover, various interagency groups within the federal government have endorsed their use, especially for regulating carcinogens where evaluation of relative risks both sharpens decision-making and helps to assure that resources are allocated in a rational and cost-effective manner.

A. Decision-Making When Uncertain Health Risks Are Presented

Regulatory decisions involving health hazards, including (but not limited to) carcinogens, must often be made in the absence of definitive information. Whenever this is the case, decision-makers must either (i) extrapolate from the best available scientific information to estimate what their actions will accomplish; or (ii) ignore the available factual data and make a decision without any estimate of the degree of risk likely to be prevented.

One advantage of the former course is that it narrows the areas of scientific uncertainty and focuses debate on the appropriateness of any assumptions required to fill gaps in the existing data. The disadvantages of making no estimate at all are many and obvious,[3] but one of the most serious is that proceeding without even a rough approximation of risk tacitly equates and treats identically all hazards

[3] *See* Main Brief 16-20, 65-68, 72-78. As the National Academy of Sciences ("NAS") has concluded, decisionmaking based on the best available information concerning the magnitude of the health risk in question "represent[s] a significant advance" over the "intuitive, ad hoc, unsystematic, and often frantic methods now used." NAS, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 45 (1975).

about which less than perfect information exists. Unless health protection resources are assumed to be limitless, making any decision without at least some estimate of the degree of risk involved will inevitably lead to misallocation and waste of finite health protection resources.

This problem is especially severe in the case of carcinogens, where the controversy has been brewing for years over whether there is or is not an absolutely safe level for exposure to cancer-causing substances. It makes no sense to treat all of the approximately 2000 potential occupational carcinogens the same[4] when carcinogenic potency can vary among substances by a factor of as much as one million.[5] Moreover, these differences in potency are only one factor that affect the degree of risk; others include variations in exposure patterns and the size of the population involved.[6] The practical importance of

[4] *See* Main Brief p. 4 n.5.

[5] *Id.* 72 n.105 *See also* (from the OSHA Cancer Policy Record) Testimony of Dr. Arthur Upton (Director of the National Cancer Institute), Tr. 319; Statement of Dr. Roy Albert (Chairman of EPA's Carcinogen Assessment Group), Exh. 219-1-A at 10; Testimony of Dr. Richard Peto (Oxford University) Tr. 2581; Statement of Dr. Joyce McCann (University of California at Berkeley) Exh. 183-5 at 18.

[6] HEW's departmental critique of the benzene standard recognized these differences. Main Brief p.73 n.107 *See also* Testimony of Grover C. Wrenn (then OSHA's Director of Health Standards Programs), OSHA Cancer Policy Record, Tr. 239-41.

these differences for regulatory decision-making is seen by comparing the benzene standard with previous OSHA standards for more potent carcinogens such as asbestos and vinyl chloride.[7]

OSHA dwells on the uncertainties of risk estimation, such as problems of extrapolating from animal studies to man, determining the levels of exposure involved in human epidemiologic studies, and selecting a dose-response function.[8] The scientific community, while recognizing that these uncertainties prevent highly accurate estimates, has nevertheless repeatedly endorsed the use of risk assessment techniques.[9] The National Research Council, for example, has concluded that even when the underlying evidence of carcinogenicity consists of animal bioassays, "a 'most probable risk' can be estimated by appropriate statistical treatment" to obtain "an upper limit

[7] For example, while the benzene standard may, based on EPA estimates, prevent one case of leukemia every 15 to 38 years, it has been estimated that OSHA's asbestos standard will prevent *1,596 deaths per year*. *See* references cited in Joint Memorandum in Opposition to Certiorari for Respondents API, *et al.*, Nos. 78-911 & 78-1036, filed January 26, 1979, at 20 n.44, 21-22 nn.48, 49.

[8] OSHA Br. 60-70. As discussed in the body of this Brief (p. 79), these do not apply in the case of benzene.

[9] Indeed, all of the literature sources cited by the Natural Resources Defense Council which discuss risk assessment actually endorse its use. *See* Crump, *et al.*, *Fundamental Carcinogenic Processes and Their Implicatons for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2793 (1976) ("[S]ome [carcinogens] may be avoided only at great expense or alternative risk, in which case 'risk versus benefit' must be evaluated."); Mantel & Schneiderman, *Estimating Safe Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH, 1379, 1380 (1975) ([C]ost benefit consideration must enter into adjudication of any safety considerations."); Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693 (1977) ("Risk assessment is . . . an essential component of regulatory decisions."). *See also* n.3 at 2c, *supra*, nn.10, 18, *infra*.

of the risk to human populations."[10] The heads of other scientific groups, such as the National Institute of Environmental Health Sciences ("NIEHS"), have reached the same conclusion.[11]

Furthermore, risk estimation has recently been endorsed by various science-oriented segments of the executive and legislative branches of the federal government. For example, the Interagency Regulatory Liaison Group, which was established in September 1977 to coordinate regulatory activities among agencies concerned with protection of the public health and the environment,[12] recently issued a Report[13] reviewing the scientific concepts and methods for quantitatively assessing human cancer risks. This Report observed that "[d]espite the uncer-

[10] NATIONAL RESEARCH COUNCIL, DRINKING WATER AND HEALTH, 27-28, 56 (1977). *See also* NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT 88 (1975) (Concluding that "[t]he statistical problems of extrapolation from experimental dose levels to very low levels . . . can be handled if care is taken in the design and analysis of the experiments and the interpretation of the results.").

[11] Testimony of Dr. David Rall (Director, NIEHS), OSHA Cancer Policy Record, Tr. 449 (Despite the uncertainties attending risk assessments, "we have got to use them."); Testimony of Dr. David Hoel (Biometry Branch Chief, NIEHS), OSHA Cancer Policy Record, Exh. 183-23 at 1-2 ("[T]here is clearly a need to assess quantitatively the risk to man at low exposure levels in order to have rational standard setting and methodology.").

[12] Initially, the IRLG was composed of the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration and OSHA. In January 1979, the Food Safety and Quality Service of the Department of Agriculture joined the IRLG as its fifth member.

[13] IRLG, *Scientific Basis for Identifying Potential Carcinogens and Estimating Their Risks*, 44 Fed. Reg. 39858, 39871-76 (July 6, 1979).

tainties" involved, "risk estimates can be and are being made, not only by some regulatory agencies but by other scientific bodies," and concluded that "preliminary observations suggest that current methodologies may not lead to serious error."[14]

The importance of risk estimation in regulatory decision-making has been emphasized even more pointedly by economic and scientific advisory panels in the Executive Office of the President. Thus, in a staff paper prepared by the President's Office of Science and Technology Policy, the President's science advisors concluded that the "determination that a particular chemical might be carcinogenic in humans is only the first step" in regulatory decision-making.[15] Additional data "must be sought and some quantitative estimate of overall risk (and uncertainty) made if regulatory agencies are to act prudently in establishing controls over the use of potential carcinogens."[16]

Moreover, in a separate analysis presented to OSHA during its recent rulemaking proceedings on its proposed Cancer Policy (*see* n.1 at 1c, *supra*), the President's Council on Wage and Price Stability strongly urged that quantitative risk estimation is

[14] *Id.* 39871. The IRLG made this observation regarding extrapolation from animal models to humans and went on to note that extrapolation of risk from one observed human population to other human exposures—the situation presented in the case of benzene—"carries less uncertainty than extrapolations from animals to humans." *Id.*

[15] OFFICE OF SCIENCE AND TECHNOLOGY POLICY, IDENTIFICATION, CHARACTERIZATION, AND CONTROL OF POTENTIAL HUMAN CARCINOGENS: A FRAMEWORK FOR FEDERAL DECISION-MAKING 14 (February 1, 1979).

[16] *Id.*

essential if OSHA is to "lay a solid foundation for the most rational regulatory decisions possible."[17]

In short, the recommendations of the President's Council and the Department of Health, Education and Welfare in connection with the benzene standard reflect a large and rapidly expanding body of scientific and governmental opinion supporting the use of risk assessment techniques in regulatory decision-making. The scientific community itself has repeatedly endorsed efforts to obtain better information concerning relative cancer risks. The purpose of the process that they recommend is not to substitute mathematical cost-benefit analyses for regulatory judgments. Instead, information concerning the health benefits and costs of regulatory options is desirable—even imperative—to organize and synthesize the available data and to provide a framework for rational decisionmaking.[18]

[17] Comments of the Council on Wage and Price Stability, OSHA Cancer Policy Record, Exh. 253 at 20. The President's Council observed that "[c]ancer risk quantification" "affords some measure, however imprecise, of the magnitude of the cancer risk, which can be an important factor in determining how to regulate a substance or what priority to assign its regulation." *Id.* The Council cautioned that in the absence of information on the magnitude of the hazard involved, "society cannot hope to allocate its scarce resources rationally to all of the ills which it faces." *Id.*

[18] As the National Academy of Sciences ("NAS") has observed:

> There is no scientific formula for making decisions .... There is no satisfactory way to summarize all the costs or benefits of regulatory options in dollars or other terms which can mathematically be added, subtracted, or compared. In short, there is no substitute for an experienced decision maker exercising

(footnote continued on next page)

B. Experience of Other Health and Safety Agencies

Because of the wide and growing acceptance of such techniques in the scientific community, risk assessment has increasingly been used by federal agencies concerned with regulating cancer-causing substances. Indeed, virtually every other federal health agency routinely assesses the degree of risk prevented (*i.e.*, the benefits) of its regulatory decisions regarding carcinogens.

For example, the Environmental Protection Agency ("EPA") routinely conducts risk assessments under an agency-wide policy, adopted in 1976, which requires "that appropriate analyses of the risks and benefits of suspected carcinogenic chemicals [be] performed as part of the regulatory process." 41 Fed. Reg. 21402, 21402-03 (May 25, 1976). The purpose of these analyses is to "formulat[e] judgments concerning the nature and magnitude of the cancer hazard from suspected carcinogens," including an estimate of the "possible impact" of each substance "on the public health at current and anticipated levels of exposure." *Id.* 21404.[19]

(footnote continued from previous page)

> good judgment. However, the techniques developed by decision theory and benefit-cost analysis can provide the decision maker with a useful framework and language for describing and discussing trade-offs, noncommensurability, and uncertainty. They can also help clarify the existence of alternatives, decision points, gaps in information, and value judgments concerning trade-offs.

NATIONAL ACADEMY OF SCIENCES, DECISIONMAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 2 (1975) (emphasis added).

[19] To accomplish this goal, EPA has created a special Carcinogen Assessment Group ("CAG") whose charge is to "conduct analyses of data related to risk and make recommendations . . . concerning the risk associated with each suspect carcinogen." *Id.* 21403. It was the CAG which developed EPA's risk estimate for benzene. A. 14-29.

In adopting this policy, EPA rejected any suggestion that these procedures might result in "regulatory paralysis" or that they are too imprecise to be useful. EPA understood that there will often be "uncertainty in the data and extrapolation techniques," but concluded that valuable information can be obtained from risk assessments "based on currently available information." *Id.* 21404-05. Thus, far from "unduly delay[ing] regulatory decisionmaking," EPA found that the use of risk assessments represents

> a significant step toward the objective of achieving real benefits in improved public health while avoiding the burdens of undesirable regulatory action.

Id. 21403. Based on its experience under this policy,[20] EPA has strongly urged OSHA to use risk estimation in its decisionmaking process as well.[21]

Like EPA, the Food and Drug Administration ("FDA") routinely uses risk estimation procedures in

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[20] EPA has completed well over 30 risk assessments under its current policy. *See* Testimony of Roy Albert (Chairman, CAG), OSHA Cancer Policy Record, Tr. 2293. Examples of such risk assessments are contained in Exhs. 219-2, 219-3-A, 291-3-E, 219-4.

[21] *See, e.g.*, the following testimony in the OSHA Cancer Policy Record: Statement of Dr. Roy Albert (Chairman, CAG), Exh. 183-46 at 6 ("[B]ecause carcinogens can vary in potency by as much as a millionfold, OSHA should strongly consider using quantitative risk assessment . . . as a factor in judging feasibility of regulatory control."); Statement of Steven Jellinek, Exh. 183-46 at 5 ("We encourage OSHA to include risk estimation in its regulatory process.").

developing its regulations,[22] and, based on this experience, has urged OSHA to do the same.[23] In fact, FDA has recently proposed to make risk assessment a regular part of its administration of the Delaney Clause.[24]

Similarly, the Consumer Product Safety Commission ("CPSC") performs risk assessments as a routine matter in regulating products that may present unreasonable risks of injury to consumers. For example, CPSC developed quantitative risk estimates for benzene and Tris in connection with its proceedings for regulating these substances. 42 Fed. Reg. 18850, 18851 (April 8, 1977)(Tris); 43 Fed. Reg. 21838, 21845 (May 19, 1978)(Benzene).

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[22] *See, e.g.*, Testimony of Donald Kennedy (Administrator, FDA), OSHA Cancer Policy Record, Tr. 513-14. For example, in connection with its proposed tolerance level for aflatoxin in consumer peanut products under Section 406 of the Food, Drug, and Cosmetic Act (21 U.S.C. § 346), FDA conducted a risk assessment to provide part of the basis for developing a final rule. 43 Fed. Reg. 8808 (March 3, 1978).

[23] Testimony of Donald Kennedy, OSHA Cancer Policy Record, Exh. 183-10 at 11 (Because "not all carcinogens are equally potent and . . . there are vast differences in the levels of human exposure, . . . I urge OSHA to use quantification of risk as one component of decision-making.").

[24] The so-called "DES proviso" to the anticancer clauses in Sections 409(c)(3)(A), 512b(d)(1)(H) and 706(b)(5)(B) of the Food, Drug and Cosmetic Act requires that there be no residue of a carcinogen in the edible portions of food-producing animals. 21 U.S.C. §§ 348(c)(3)(A), 360b(d)(1)(H), & 376(b)(5)(B). Because increasingly sensitive analytical techniques threaten to turn these requirements into a ban on the use of valuable growth-stimulants in animal feed, FDA proposes to utilize quantitative risk estimation to determine the residue concentration that is expected to present a cancer risk of one-in-one million over a lifetime, and to require measurement techniques which will not detect lower concentrations. 44 Fed. Reg. 17070 (March 20, 1979).

The experience of EPA, FDA, CPSC and other federal agencies[25] in using quantitative risk assessments to develop regulations for carcinogens reflects the widespread and long-standing use of similar techniques in many areas of regulation.[26] In short, there is simply no foundation for any claim that these procedures will contribute nothing or will result in regulatory paralysis.

C. The Experience of OSHA

Any claim by OSHA that quantitative risk estimation is impossible or not useful is fully laid to rest when OSHA's own practices are examined. Although hardly a model of consistency, OSHA, both in public declarations and in developing other standards, has recognized the value of risk assessment, and even cost-benefit analyses.

Perhaps the best example of OSHA's ability to assess quantitatively the benefits of its standards is a recent report to Congress in which OSHA attempts

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[25] As far back as 1960, for example, the Nuclear Regulatory Commission (then the Atomic Energy Commission) issued regulations concerning occupational and ambient exposure to cancer-causing radiation which were based on quantitative risk estimates. *See* 25 Fed. Reg. 8595 (September 7, 1960); FEDERAL RADIATION COUNCIL, BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS, Report No. 1 (May 13, 1960). *See also*, 35 Fed. Reg. 18385 (December 3, 1970); NATIONAL BUREAU OF STANDARDS, MAXIMUM PERMISSIBLE AMOUNTS OF RADIOISOTOPES IN THE HUMAN BODY AND MAXIMUM PERMISSIBLE IN THE AIR AND WATER, NBS Handbook 69 (April 1959).

[26] The National Highway Traffic Safety Administration ("NHTSA") and the Federal Aviation Administration ("FAA"), for example, have for years conducted careful studies of the risks and benefits of alternative regulations in the area of transportation safety. For example, NHTSA employed detailed risk and benefit data in connection with its motor vehicle safety standard for air bags. *See* 42 Fed. Reg. 34288, 34298-99 (July 5, 1977); 41 Fed. Reg. 31860 (July 30, 1976). The FAA uses a similar approach. *See, e.g.*, FAA, *Establishment Criteria for Airport Traffic Control Towers*, Report No. ASP-75-4, (U.S. Dep't of Transp., October 1975). *See also* n.2 at 1c, *supra*.

to justify its 1978 standard for cotton dust.[27] In this Report, OSHA estimated the risk of exposure at various levels and in various work operations and projected the costs and benefits (expressed as the number of cases of disease avoided annually) of the alternative exposure limits that it examined.[28] OSHA's presentation to Congress included elaborate and detailed analyses of the incremental costs and benefits of possible alternative standards,[29] as well as "marginal analyses . . . of the major industry subgroups" under each alternative.[30] OSHA rejected more stringent standards on the ground that they would have been less "cost-effective" than the one it had chosen and they would have required "disproportionately large compliance costs for relatively small health gains."[31]

The Cotton Dust Report is a concrete reflection of the increasing recognition by OSHA's leading spokespersons that risk quantification is a valuable tool in arriving at regulatory decisions. Thus, in a recent speech, Secretary of Labor Marshall firmly declared that "we are beginning to quantify the benefits of regulations that improve . . . worker safety and health," and added:

> It does no harm to our cause to acknowledge both the costs and benefits of regulation. It helps us decide more intelligently

[27] U.S. Dep't of Labor, *Report to the Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies* (May 14, 1979).

[28] *Id.* 81-97.

[29] *See, e.g., id.* Table VI-1 at p. 82.

[30] *Id.* 81.

[31] *Id.* 65. The textile industry has challenged the cotton dust standard on the ground, *inter alia*, that it would be much more costly and would provide fewer health benefits than OSHA has claimed, thereby being far less cost-effective as well.

> which goals are more important and how to reach them.[32]

Dr. Eula Bingham, the head of OSHA, took a similar position in recent testimony before the Senate Appropriations Committee.[33]

These recent actions and pronouncements reflect earlier efforts by OSHA to use quantitative and qualitative information on health risks in developing occupational health standards.[34] For example, in its 1974 rule setting standards for 14 different carcinogens, OSHA significantly modified the regulatory requirements based on careful distinctions concerning the carcinogenic potencies of the substances under consideration.[35]

[32] March 24, 1979, speech of Secretary of Labor Ray Marshall to the League of Women Voters at 3, 8. *See* OCCUP. SAFETY & HEALTH REP. (BNA) 1606 (March 29, 1979).

[33] Dr. Bingham testified that OSHA does "incremental cost-benefit analyses . . . all the time," and that such analyses are a "key factor" in developing a new regulation. *Hearings on Dep'ts of Labor and Health, Education and Welfare and Related Agencies' Appropriations for Fiscal 1980, before the Senate Comm. on Appropriations*, 96th Cong., 1st Sess. 490 (Feb. 8, 1979).

[34] As far back as 1974, OSHA recognized that the benefits of its standards "cannot be estimated with certainty," but nevertheless stated that it was "exploring methods to obtain the data necessary to begin *quantitatively* evaluating" "the entire range of financial, social, and other real but indirect benefits which accrue" from its standards. *The President's Report on Occupational Safety and Health* 15 (OSHA Annual Report 1974) (emphasis added).

[35] In that case, OSHA excluded from the coverage of its standards some exposure to eight of the fourteen carcinogens involved because "the record contain[ed] very little information" concerning the "carcinogenic potentiality" of exposure at the levels involved and concerning the economic benefits of the substances. 39 Fed. Reg. 3756, 3759 (Jan. 29, 1974). By contrast, more stringent controls were imposed on the remaining six

(footnote continued on next page)

More recently, OSHA purported to use a risk estimation/cost-effectiveness approach in developing its Lead Standard. In that case, as in the case of its Cotton Dust Report, OSHA purported to provide an elaborate incremental analysis of the relative health benefits (in terms of reduced blood-lead levels) that would be realized at various exposure levels.[36] The estimated benefits of various alternatives were compared not only to the current level but to each other.[37]

In sum, the present contention of OSHA's lawyers that risk assessment is not a useful regulatory technique simply cannot be credited. The substantial experience of other federal health agencies, and even that of OSHA itself in several instances, establishes that these procedures are both feasible and immensely useful in helping to clarify and rationalize regulatory decisionmaking for carcinogens and other health hazards.

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substances because they were "known to be potent carcinogens." *Id.*

Similarly, OSHA used quantitative risk information in connection with its 1974 proposed noise standard. Bolt, Baranack & Newman, Inc., *Economic Impact Analysis of Proposed Noise Control Regulation*, Rep. No. 3246, April 21, 1976, prepared for the U.S. Dep't of Labor, OSHA. *See* 29 Fed. Reg. 37773 (Oct. 24, 1974).

[36] *See* 43 Fed. Reg. 52952, 52967-72 (November 14, 1978); 43 Fed. Reg. 54354, 54427-40 (November 21, 1978).

[37] Interestingly enough, OSHA concluded that this "evaluation of the relationship between the costs and benefits [of the Lead Standard] meets the test enunciated by the Fifth Circuit" in the case now before this Court. 43 Fed. Reg at 54431.